

中国药典  
中药和西药  
高效液相色谱图集

**Compendium**  
of HPLC Applications for  
Traditional Chinese Medicine  
and Chemical Drugs in  
China Pharmacopoeia



Agilent Technologies

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for Traditional Chinese Medicine and  
Chemical Drugs in China Pharmacopoeia**

## Preface

This compendium is a collection of analysis methods for traditional Chinese medicine and chemical drugs in the China Pharmacopoeia, which use high performance liquid chromatography (HPLC) as the analysis technique. HPLC was first adopted in the China Pharmacopoeia as an analysis technique in 1985 on account of its selectivity and sensitivity. The widespread use of HPLC instrumentation in China has led to an increase in the adoption of the technique in the China Pharmacopoeia. The 2005 edition included 1366 applications of HPLC, which has now become the most popular analysis method in the Pharmacopoeia.

This compendium is divided into two parts. The first part describes HPLC analysis methods for traditional Chinese medicine from Volume I of the 2005 edition of the China Pharmacopoeia. For many methods, both the Latin and English names are given. Part two of the compendium describes the HPLC methods for chemical drugs from Volume II of the 2005 edition of the China Pharmacopoeia.

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# **Traditional Chinese Medicine**

# Japanese Ardisia Herb (*Herba Ardisiae Japonicae*) – 矮地茶

## Sample source

Commercially available Japanese Ardisia Herb

## Chemical reference substances

Bergenin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1532-200202)

## Preparation of test solution

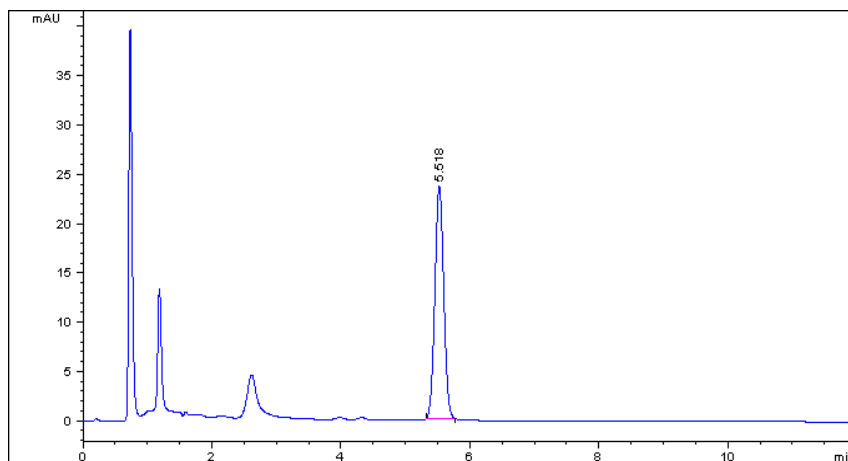
Accurately weigh 0.1 g of the fine powder in a conical flask. Accurately add 10 mL of methanol, weigh, treat ultrasonically for 40 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (20:80)
- Detector wavelength: 275 nm
- Flow rate: 1.0 mL/min
- Injection volume: 2 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Bergenin	3.599	5.518	23.65	227.6	7784	1.04

# Aifu Nuangong Pills (*Aifu Nuangong Wan*) – 艾附暖宫丸

## Sample source

Commercially available Aifu Nuangong Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0736-200220)

## Preparation of test solution

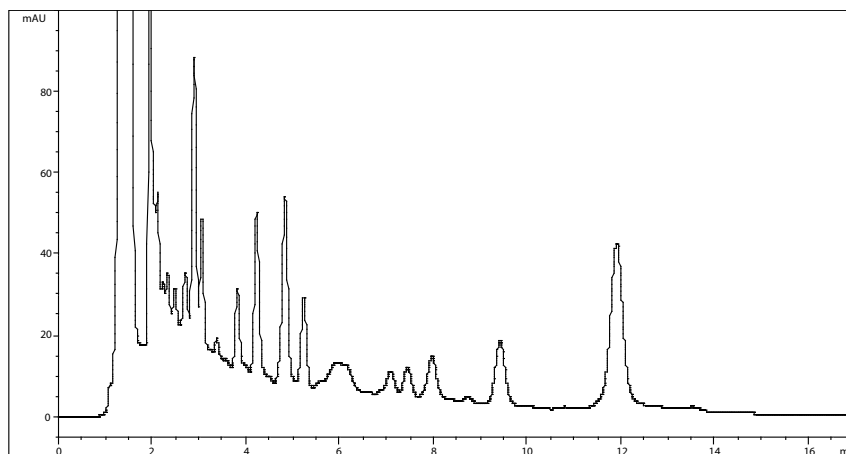
Cut the pills into pieces. Accurately weigh 0.8 g in a stoppered conical flask, accurately add 10 mL of 50 % methanol, stopper well, and weigh. Treat ultrasonically for 40 minutes, allow to cool, weigh again, replenish the lost weight with 50 % methanol, shake well, filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.1 % phosphoric acid (12:88)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	8.928	11.91	39.20	715.5	10274	0.99

# Anshen Buxin Pills (*Anshen Buxin Wan*) – 安神补心丸

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## Sample source

Commercially available Anshen Buxin Pills

## Chemical reference substances

Schisandrin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110857-200203)

## Preparation of test solution

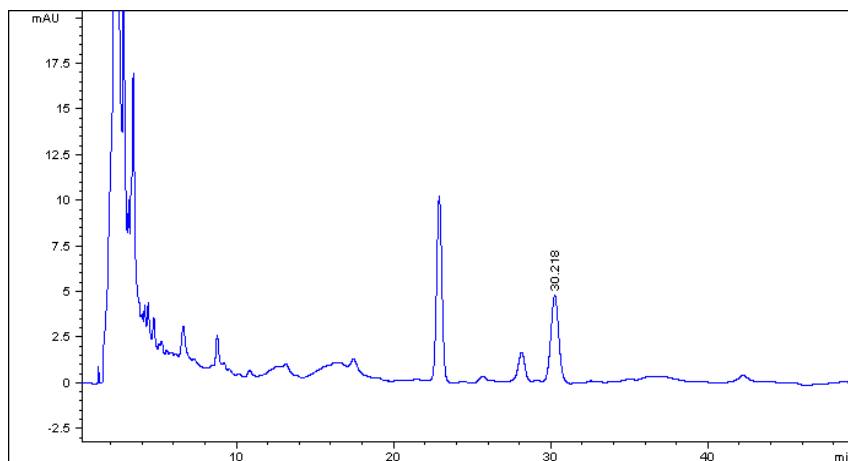
Accurately weigh 15 pills, grind to a fine powder and mix well. Accurately weigh 0.5 g, accurately add 25 mL of methanol, weigh, treat ultrasonically for 30 minutes, allow to reach room temperature, weigh again and replenish the lost weight with methanol. Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 42 °C
- Mobile phase: methanol-water (50:50)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Schisandrin	11.087	30.218	4.76	165.0	17750	1.02

# Anshen Capsules (*Anshen Jiaonang*) – 安神胶囊

## Sample source

Commercially available Anshen Capsules

## Chemical reference substances

Schisandrin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110857-200203)

## Preparation of test solution

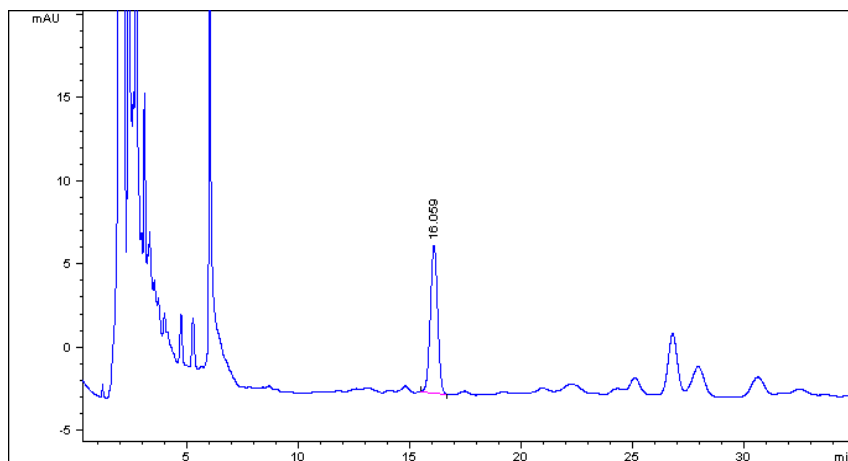
Grind the content of the capsules to a fine powder and mix well. Accurately weigh 1.0 g of the powder in a stoppered conical flask. Accurately add 25 mL of a mixture of chloroform and methanol (2:1), weigh, treat ultrasonically for 40 minutes, allow to cool, weigh again, replenish the lost weight with the mixture of chloroform and methanol (2:1), mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (58:42)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Schisandrin	5.424	16.059	8.89	201.6	11701	0.98

# Anzhong Tablets (*Anzhong Pian*) – 安中片

## Sample source

Commercially available Anzhong Tablets

## Chemical reference substances

Ammonium glycyrrhizinate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0731-9704)

## Preparation of test solution

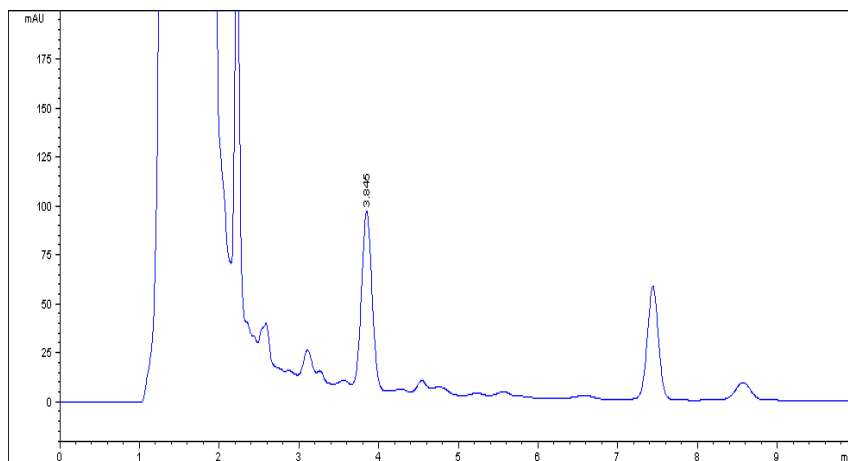
Accurately weigh 20 tablets or film-coated tablets with coating removed, grind well, accurately weigh 1 g in a stoppered conical flask, accurately add 10 mL of the mobile phase, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with the mobile phase, and shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: methanol-0.2mol/L ammonium acetate-glacial acetic acid (68:32:1)
- Detector wavelength: 252 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Glycyrrhizinic acid	2.204	3.845	89.95	815.3	4135	1.00



# Bazhen Yimu Pills (*Bazhen Yimu Wan*) – 八珍益母丸

## Sample source

Commercially available Bazhen Yimu pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0736-200220)

## Preparation of test solution

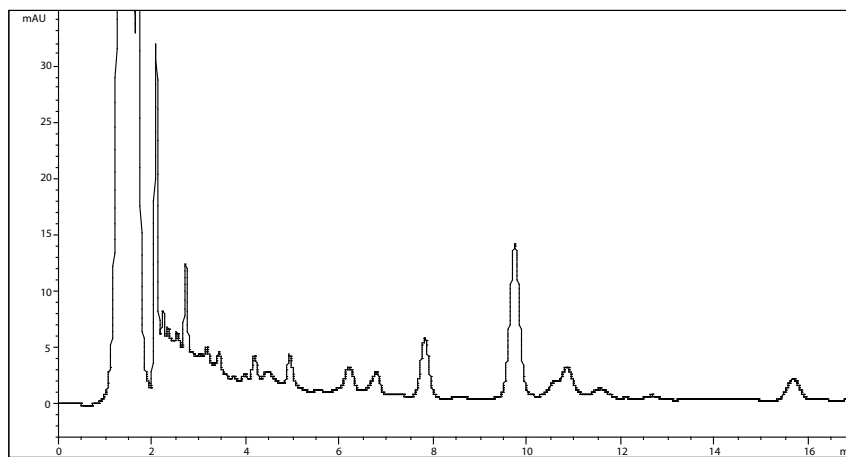
Cut a quantity of the pills into pieces and mix well, take 0.2 g of the pieces and accurately weigh in a stoppered conical flask. Accurately add 10 mL of dilute ethanol, stopper well, weigh and treat ultrasonically for 40 minutes. Allow to cool to room temperature, weigh again and replenish the lost weight with dilute ethanol. Mix thoroughly, centrifuge and use the supernatant liquid as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid solution (13:87)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	7.116	9.739	13.46	198.3	10099	1.00

# Bazheng Mixture (*Bazheng Heji*) – 八正合剂

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## Sample source

Commercially available Bazheng Heji

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110749-200309)

## Preparation of test solution

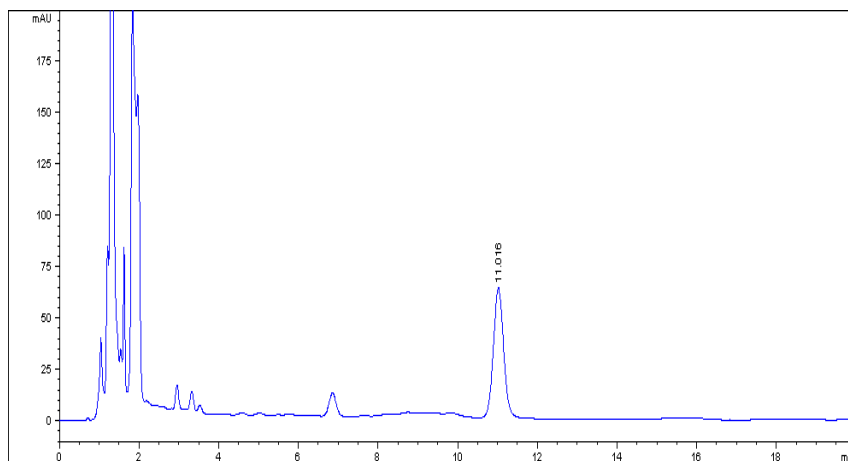
Accurately measure 5 mL of the mixture in a 50 mL volumetric flask, dilute to volume with dilute ethanol and mix well, centrifuge and use the supernatant liquid as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 μm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (10:90)
- Detector wavelength: 238 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



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Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide	6.344	11.016	63.14	1120.6	9221	1.05

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# Chinaroot Greenbrier Rhizome (*Rhizoma Smilacis Chinae*) – 菝葜

## Sample source

Commercially available Chinaroot Greenbrier Rhizome

## Chemical reference substances

Diosgenin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1539-200201)

## Preparation of test solution

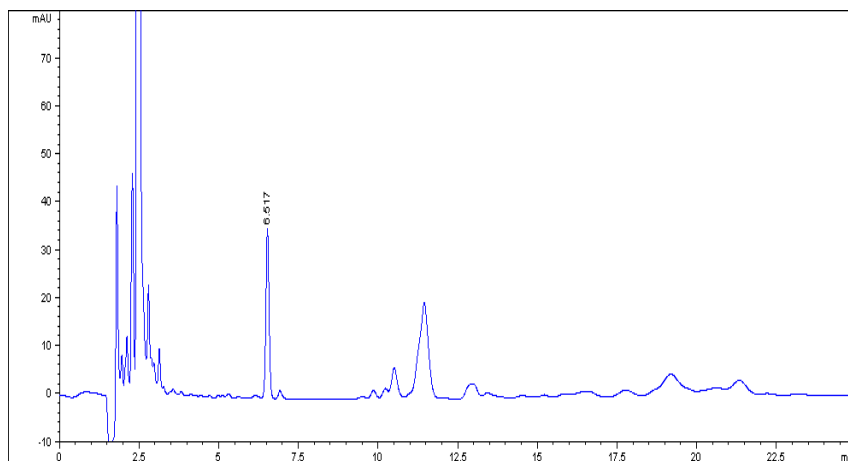
Accurately weigh 8 g of the powder into a Soxhlet extractor (No. 2 sieve), add a quantity of ethanol, and soak overnight, heat under reflux until the extract is colorless. Recover the solvent to about 100 mL, add 16 mL of hydrochloric acid, heat under reflux on a water bath for 2 hours, allow to cool, and extract with four 40 mL quantities of petroleum ether (60-90 °C) by shaking. Combine the extracts, evaporate the solvent to dryness. Dissolve the residue in acetonitrile and transfer to a 10 mL volumetric flask, dilute with acetonitrile to volume, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (72:28)
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Diosgenin	1.607	6.517	35.20	243.4	21754	1.05

# Baidai Pills (*Baidai Wan*) – 白帶丸

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## Sample source

Commercially available Baidai Wan

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200209)

## Preparation of test solution

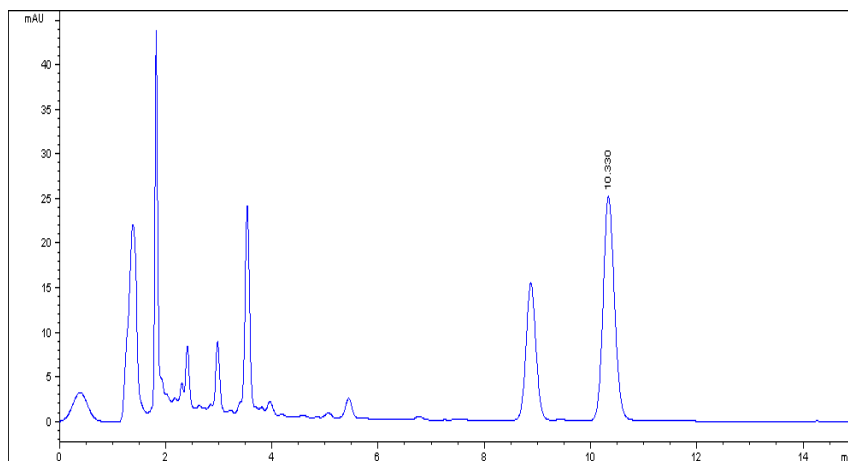
Grind a quantity of the pills to a fine powder and mix well. Accurately weigh about 0.2 g of the powder, accurately add 25 mL of a mixture of methanol and hydrochloric acid (1:100), weigh, heat under reflux for 30 minutes, allow to cool to room temperature, weigh again and replenish the lost weight with a mixture of methanol and hydrochloric acid (1:100). Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.05mol/L potassium dihydrogen phosphate solution (adjust to pH 5.05 with sodium hydroxide TS) (25:75)
- Detector wavelength: 346 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	5.886	10.33	25.17	370.3	11860	1.10

# White Peony Root (*Radix Paeoniae*) – 白芍

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## Sample source

Commercially available White Peony Root (Zhejiang)

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0736-200220)

## Preparation of test solution

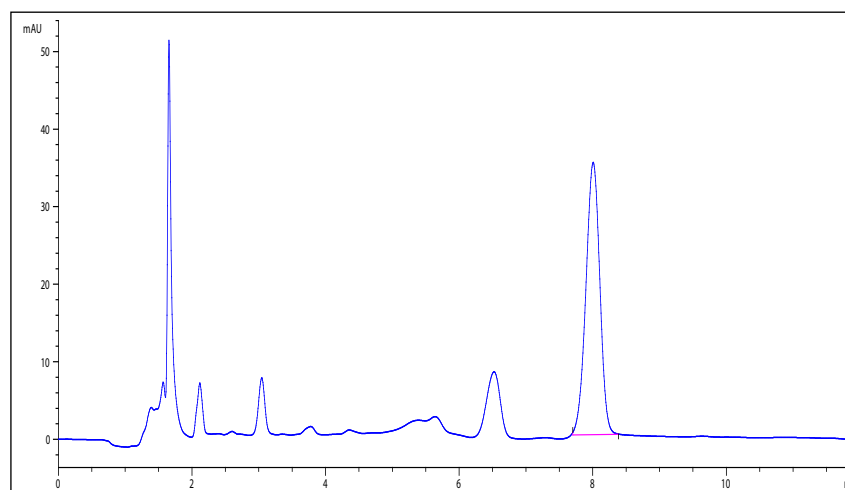
Accurately weigh 0.1 g of the powder in a 50 mL volumetric flask, add 35 mL of diluted ethanol, treat ultrasonically for 30 minutes, allow to cool and dilute with dilute ethanol to volume, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (14:86)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



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Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin		8.007	35.12	507.6	7126	0.96

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# Dahurian Angelica Root (*Radix Angelicae Dahuricae*) – 白芷

## Sample source

Commercially available Dahurian Angelica Root

## Chemical reference substances

Imperatorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110826-200307)

## Preparation of test solution

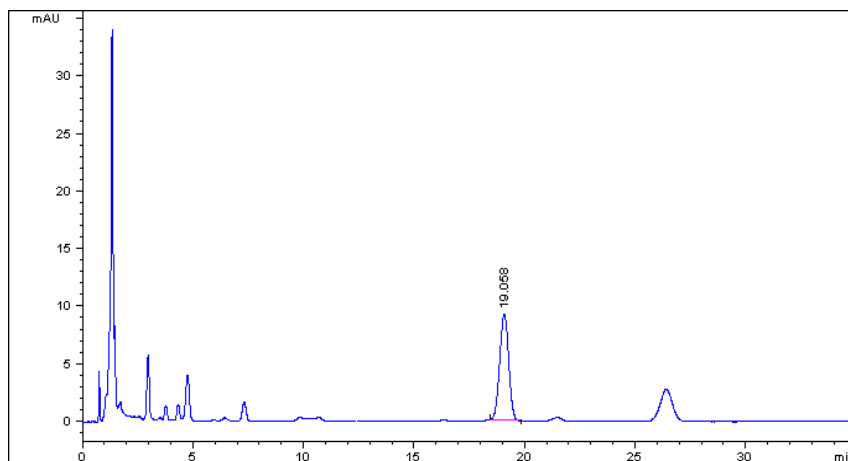
Accurately weigh 0.2 g of the powder in a 25 mL volumetric flask, add 45 mL of methanol, treat ultrasonically for 60 minutes, allow to cool and dilute with methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (55:45)
- Detector wavelength: 300 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Imperatorin	14.88	19.058	9.22	263.2	10316	0.99

# Baihe Gujin Pills (*Baihe Gujin Wan*) – 百合固金丸

## Sample source

Commercially available Baihe Gujin Wan

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

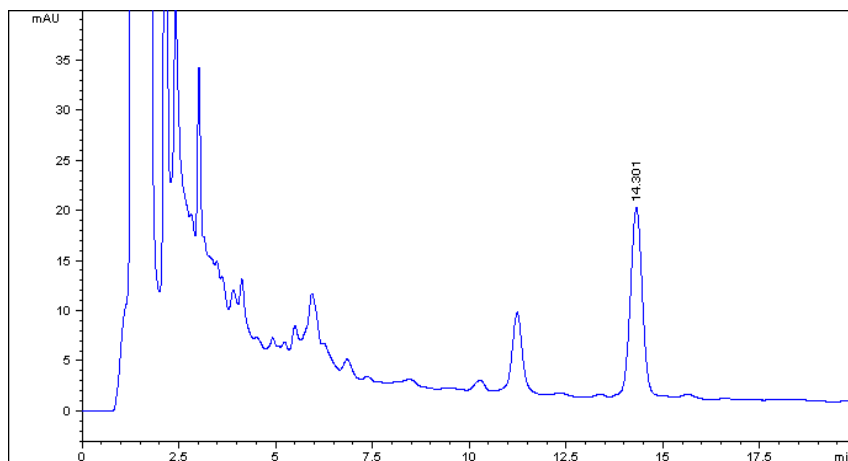
Cut the pills into pieces and mix well. Accurately weigh about 1 g in a stoppered conical flask, accurately add 10 mL of dilute ethanol, stopper well, weigh and allow to stand overnight. Treat ultrasonically for 40 minutes, allow to cool to room temperature, weigh again and replenish the lost weight with dilute ethanol. Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (11:89)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	10.918	14.301	18.61	382.7	11043	1.00

# Bailing Capsules (*Bailing Jiaonang*) – 百令胶囊

## Sample source

Commercially available Bailing Jiaonang

## Chemical reference substances

Adenosine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110879-200202)

## Preparation of test solution

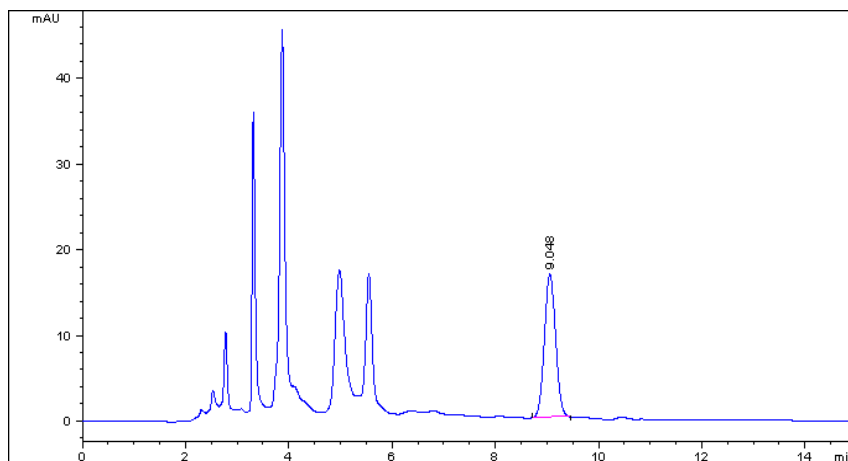
Accurately weigh 0.5 g of the content of the capsule in a stoppered conical flask, mix well. Accurately add 20 mL of ether, stoppered tightly, soak for 30 minutes, filter and discard ether. Evaporate the residue to dryness. Accurately add 50 mL of 0.5 % phosphoric acid, stopper tightly, accurately weigh, treat ultrasonically for 30 minutes, cool, accurately weigh again, replenish the lost weight with 0.5 % phosphoric acid, mix well and allow to stand. Filter the supernatant liquid through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Bonus-RP, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880668-901)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-40 mmol/L potassium dihydrogen phosphate (6:94)
- Detector wavelength: 260 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Adenosine	2.619	9.048	16.74	252.5	8533	1.05



# Baoking Granules (*Baoking Keli*) – 宝咳宁颗粒

## Sample source

Commercially available Baoking Keli

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

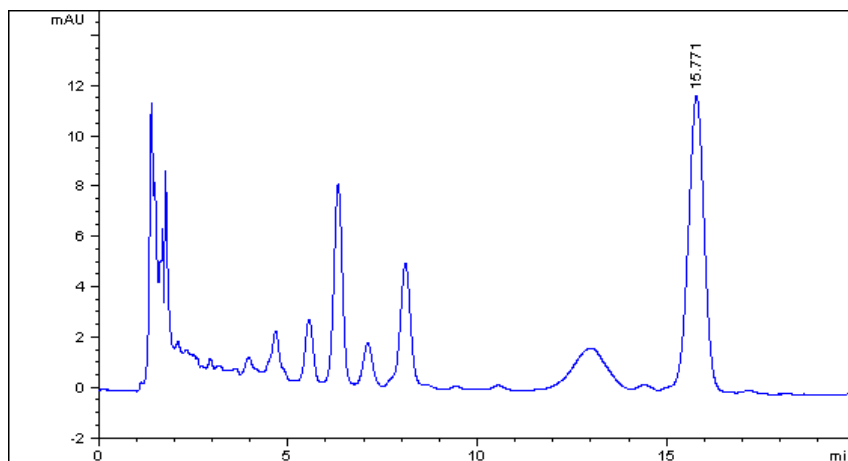
Accurately weigh 0.5 g of the granules in a stoppered conical flask, grind to a powder, accurately add 50 mL of dilute ethanol, weigh, heat under reflux for 1 hour, allow to cool to room temperature, weigh again and replenish the lost weight with dilute ethanol. Mix thoroughly, allow to stand, filter the supernatant liquid, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-phosphoric acid (41:59:0.2)
- Detector wavelength: 278 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	9.514	15.771	11.76	343.3	7010	0.96

# Baohe Pills (*Baohe Wan*) – 保和丸

## Sample source

Commercially available Baohe Wan

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110721-200211)

## Preparation of test solution

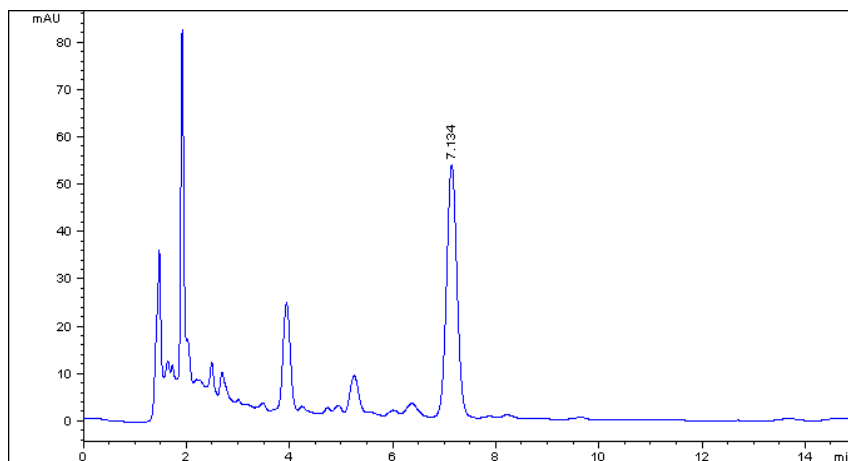
Cut the pills into pieces, take about 5 g, accurately weigh, add a quantity of kieselguhr, grind well, transfer to a Soxhlet extractor, add 80 mL of petroleum ether (60-90 °C), heat under reflux for 2.5 hours. Discard the petroleum ether extract and evaporate the residue to dryness, add 80 mL of methanol, heat under reflux until the extract solution is colorless, allow to cool and filter. Transfer the filtrate to a 100 volumetric flask, wash the container with a small quantity of methanol several times, filter the washings into the same flask, dilute with methanol to volume, and mix well. Accurately transfer 5 mL to a 10 mL volumetric flask, dilute with mobile phase to volume. Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-6.8 % glacial acetic acid (32:68)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	4.945	7.134	53.41	742.4	6183	1.03

# Baohe Watered Pills (*Baohe Wan (Shuiwan)*) – 保和丸 (水丸)

## Sample source

Commercially available Baohe Watered Pills

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0721-200211)

## Preparation of test solution

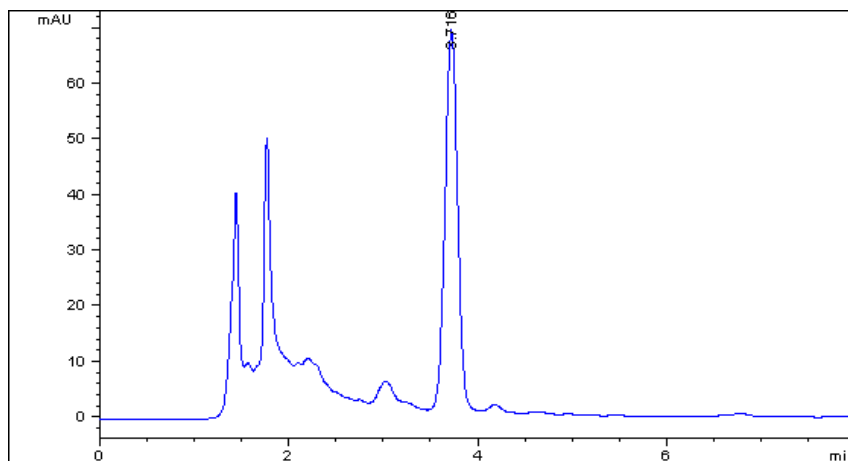
Grind a quantity of the pills to a fine powder and mix well. Accurately weigh about 2 g of the powder in a Soxhlet extractor, add 80 mL of petroleum ether (60-90 °C), heat under reflux for 2-3 hours. Discard the petroleum ether extract and evaporate the residue to dryness, add 80 mL of methanol, heat under reflux until the extract solution is colorless, allow to cool and filter. Transfer the filtrate to a 100 mL of a volumetric flask, wash the container with a small quantity of methanol several times, filter the washings into the same flask, dilute with methanol to volume and mix well. Accurately transfer 5 mL to a 10 mL volumetric flask, dilute with mobile phase to volume. Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 40 °C
- Mobile phase: methanol-glacial acetic acid-water (38:6:56)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin		3.716	68.46	631.6	3861	1.00

# Baoji Pills (*Baoji Wan*) – 保济丸

## Sample source

Commercially available Baoji Wan

## Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1.0729-200006, 2.0730-9204)

## Preparation of test solution

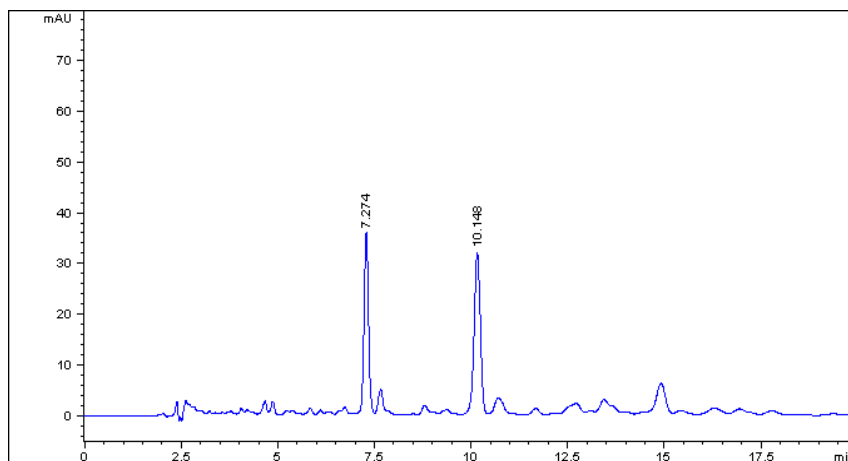
Accurately weigh 1.0 g of the fine powder in a stoppered conical flask, add 100 mL of petroleum ether (30-60 °C) and treat ultrasonically for 30 minutes, and filter. Treat the residue ultrasonically again with 50 mL of petroleum ether (30-60 °C) for 30 minutes and filter. Combine the filtrates, evaporate to dryness, dissolve the residue in methanol, transfer to a 10 mL volumetric flask, dilute to volume with methanol, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18, 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-glacial acetic acid-water (60:4:40)
- Detector wavelength: 294 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Honokiol	1.910	7.274	35.87	293.9	18660	1.02
Magnolol	3.059	10.148	31.71	351.9	20001	0.95

# Biyang Tablets (*Biyang Pian*) – 鼻炎片

## Sample source

Commercially available Biyang Tablets

## Chemical reference substances

Magnolol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110882-200203)

## Preparation of test solution

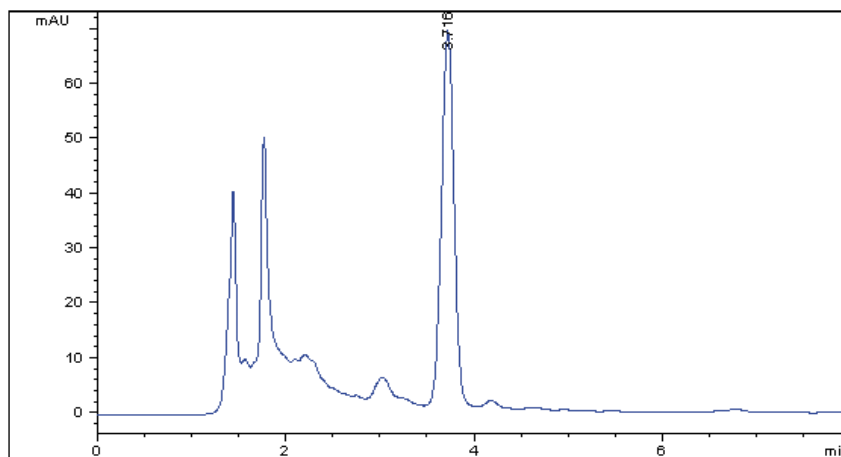
Accurately weigh 10 tablets, remove the coating, grind to a fine powder. accurately weigh 0.4 g, in a stoppered conical flask, accurately add 10 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again and replenish the lost weight with methanol, mix well and filter. Accurately measure 5 mL of the successive filtrate and apply to a neutral alumina column (100-200 mesh, 10 mm in internal diameter, packed with 2 g of neutral alumina by methanol, washed previously with methanol) and elute with a quantity of methanol, collect eluent in a 10 mL volumetric flask until almost to the volume, dilute with methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (38:62)
- Detector wavelength: 278 nm
- Flow rate: 1.0 mL/min
- Injection volume: 15 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin		3.716	68.46	631.6	3861	1.00

# Biyuanshu Mixture (*Biyuanshu Koufuye*) – 鼻渊舒口服液

## Sample source

Commercially available Biyuanshu Mixture

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110749-200309)

## Preparation of test solution

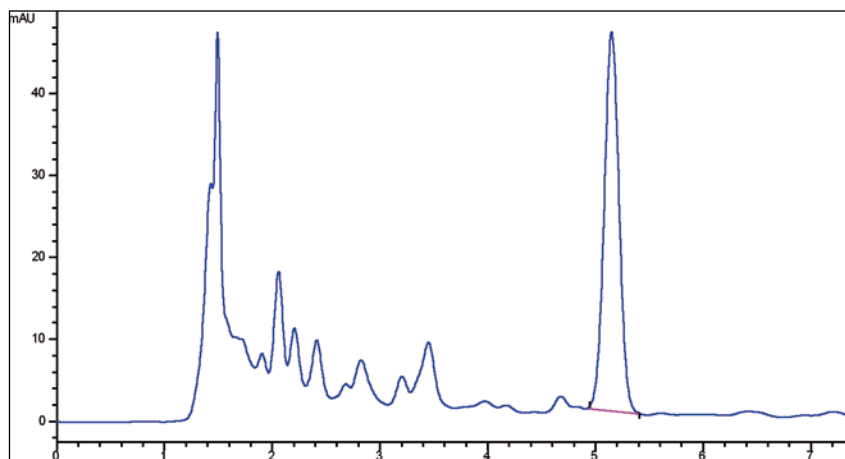
Accurately measure 0.1 mL of the mixture in a 10 mL volumetric flask, dilute with 50 % methanol to volume and shake thoroughly, filter through a millipore membrane (0.45  $\mu\text{m}$ ), filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: methanol-0.2 % phosphoric acid solution (30:70)
- Detector wavelength: 238 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide	3.295	5.154	46.33	444.1	6790	0.99

# Malaytea Scurfpea Fruit (*Fructus Psoraleae*) – 补骨脂

## Sample source

Commercially available Malaytea Scurfpea Fruit

## Chemical reference substances

1. Psoralen, 2. Isopsoralen (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110739-200309 2. 110738-200309)

## Preparation of test solution

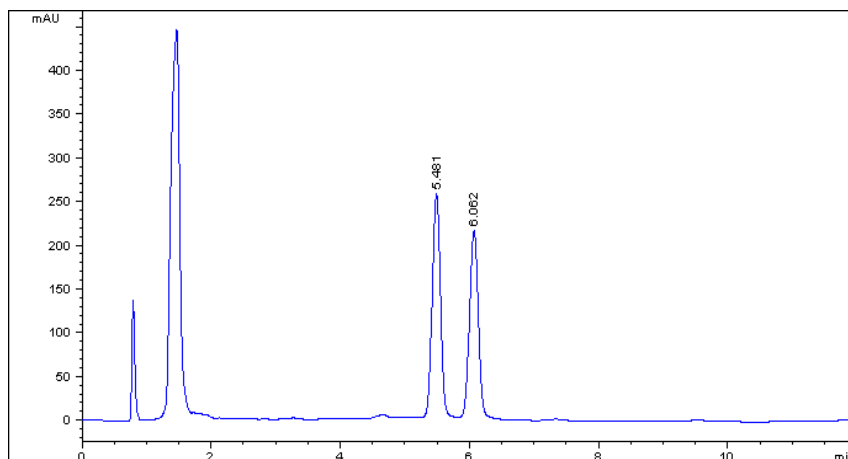
Accurately weigh 0.05 g of the fine powder in a Soxhlet extractor (No. 3 sieve), add a quantity of methanol and heat under reflux for 2 hours, allow cool and transfer to a 10 mL volumetric flask, dilute with methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (55:45)
- Detector wavelength: 246 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Psoralen	3.567	5.481	255.52	2265.1	8800	1.01
Isopsoralen	4.052	6.062	213.82	2034.9	9393	1.02

# Bushen Yiniao Tablets (*Bushen Yiniao Pian*) – 补肾益脑片

## Sample source

Commercially available Bushen Yiniao Tablets

## Chemical reference substances

1. Psoralen, 2. Isopsoralen (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110739-200309, 2. 110738-200309)

## Preparation of test solution

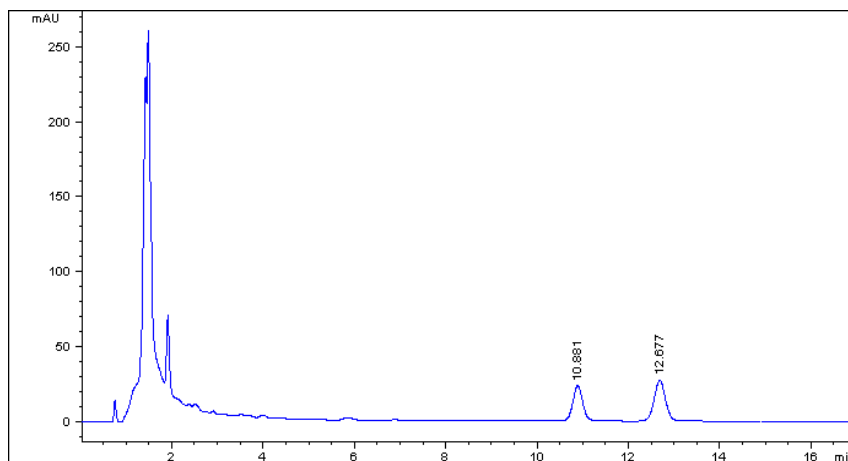
Accurately weigh 20 tablets, remove the coating, grind well. Accurately weigh 0.3 g in a 5 mL volumetric flask. Accurately add 5 mL of methanol, weigh, treat ultrasonically for 30 minutes, cool, weigh again, replenish the lost the weight with methanol, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (42:58)
- Detector wavelength: 245 nm
- Flow rate: 1.0 mL/min
- Injection volume: 2 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USPT <sub>f</sub>
Psoralen	8.067	10.881	23.34	344.1	12877	1.05
Isopsoralen	9.564	12.677	26.96	457.4	13206	1.04



# Buzhong Yiqi Watered Pills (*Buzhong Yiqi Wan (Shui Wan)*)

补中益气丸，水丸

## Sample source

Commercially available Buzhong Yiqi Watered Pills

## Chemical reference substances

Astragaloside IV (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0781-9807)

## Preparation of test solution

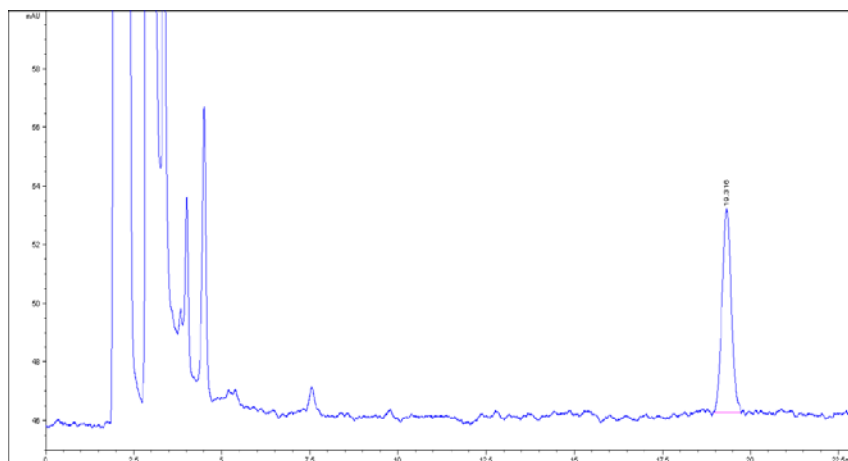
Grind a quantity of the pills to a fine powder and mix well. Accurately weigh about 4 g of the powder in a Soxhlet extractor, add a quantity of methanol, heat under reflux for 7 hours. Evaporate the extracts to dryness, and dissolve residue in 25 mL of warm water, wash with two 20 mL quantities of ether, extract the water layer with six 20 mL quantities of n-butanol saturated with water. Combine the n-butanol extracts, wash with three 40 mL quantities of ammonia. Evaporate the n-butanol extracts to dryness, and dissolve residue in methanol, and transfer to 10 mL volumetric flask, dilute with methanol to volume. Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (35:65)
- Evaporator tube temperature: 65°C
- Air flow rate: 2.0 mL/min
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series binary pump
- Agilent 1200 Series manual injector
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD Alltech 2000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
astragaloside IV	6.726	19.316	6.94	127.0	26364	1.04

# Chenxiang Huaqi Pills (*Chenxiang Huaqi Wan*) – 沉香化气丸

## Sample source

Commercially available Chenxiang Huaqi Pills

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110721-200211)

## Preparation of test solution

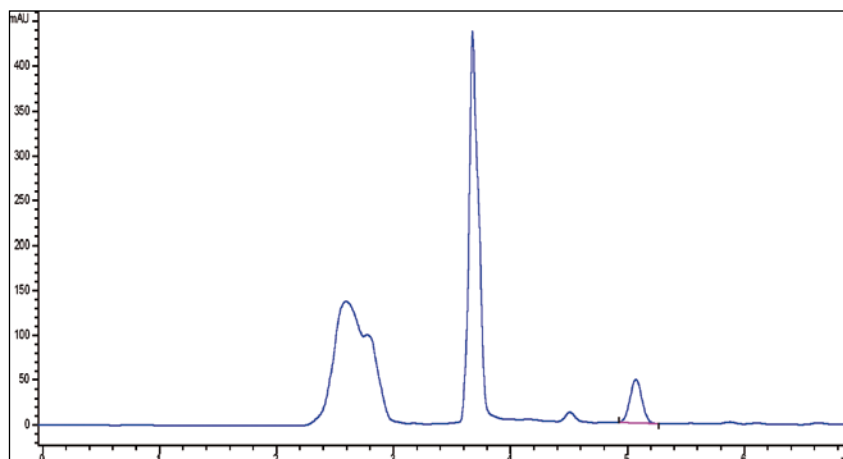
Grind a quantity of the pills to a fine powder and mix well. Accurately weigh 0.5 g of the powder in a Soxhlet extractor, add a quantity of methanol, heat under reflux for 3 hours. Transfer the extracts to a 50 mL volumetric flask, wash the container with a quantity of methanol several times, combine the washings with the extracts in the same flask, dilute with methanol to volume, and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (28:72)
- Detector wavelength: 283 nm
- Flow rate: 0.8 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	0.624	5.073	48.14	343.6	11929	0.98

# Chitong Xiaoyanling Granules (*Chitong Xiaoyanling Keli*)

## 齿痛消炎灵颗粒

### Sample source

Commercially available Chitong Xiaoyanling Granules

### Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0721-200211)

### Preparation of test solution

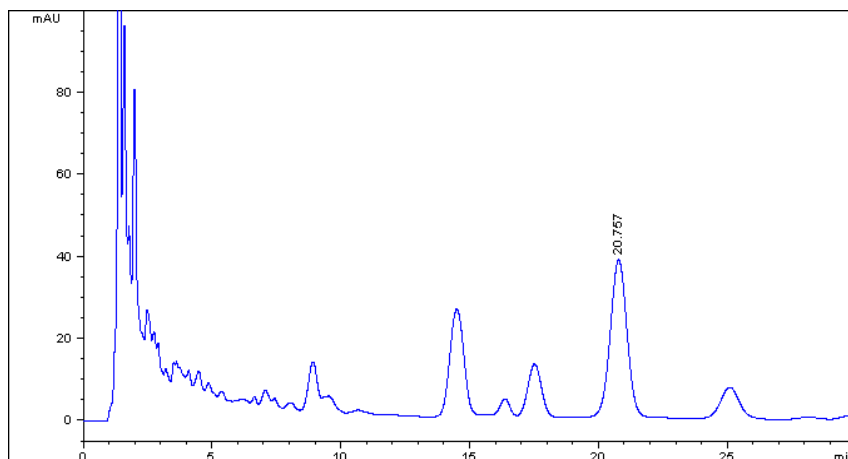
Grind a quantity of the granules to a fine powder and mix well. Accurately weigh 2 g of the fine powder in a conical flask. Add accurately 25 mL of methanol, weigh, treat ultrasonically for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 μm (993967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (33:67)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	12.838	20.757	38.39	1718.9	4955	1.01

# Paris Root (*Rhizoma Paridis*) – 重楼

## Sample source

Commercially available Paris Root

## Chemical reference substances

1. Chonglou saponin I, 2. Chonglou saponin II (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 111590-200402, 2.111591-200301)

## Preparation of test solution

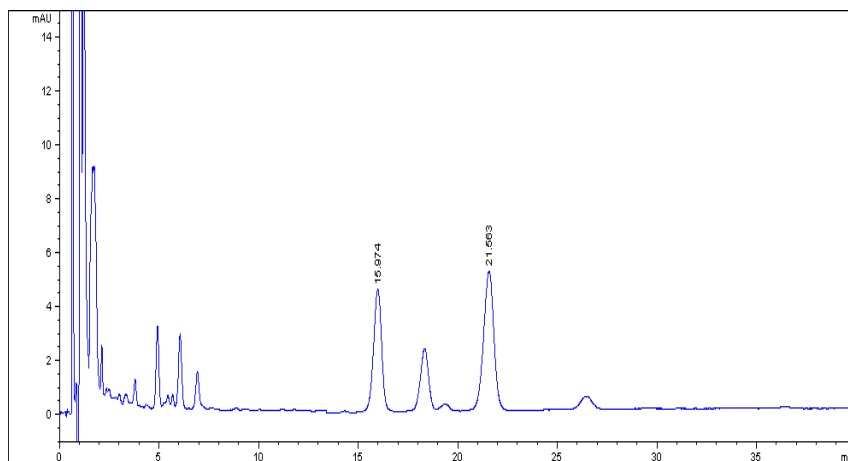
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 25 mL of ethanol and weigh. Treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost solvent with ethanol and mix well. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (42:58)
- Detector wavelength: 210 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chonglou saponin I	9.650	15.974	4.52	126.1	7649	0.95
chonglou saponin II	13.375	21.563	5.15	183.1	8833	0.94

# Nippon Yam Rhizome (*Rhizoma Dioscoreae Nipponicae*) – 穿山龙

## Sample source

Commercially available Nippon Yam Rhizome

## Chemical reference substances

Diosgenin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111539-200201)

## Preparation of test solution

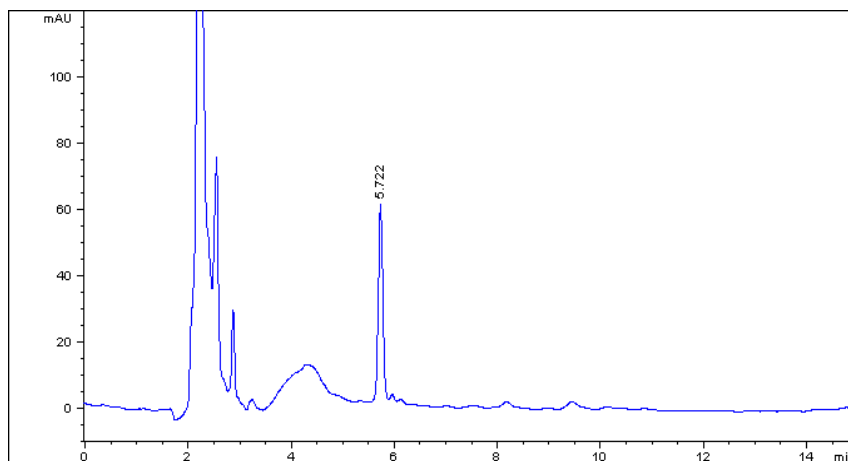
Accurately weigh 1 g of the powder in a conical flask, add 50 mL of methanol, treat ultrasonically for 30 minutes, filter, and rinse the residue with 20 mL of methanol. Combine the methanol solutions and evaporate to dryness. Dissolve the residue in successive quantities of 10 mL, 5 mL and 5 mL of 3 mol/L hydrochloric acid solution, successively transfer to a conical flask, heat to hydrolyze on a water bath for 30 minutes, allow to cool, add 30 mL of chloroform, heat under reflux for 15 minutes, repeat the extraction with chloroform in the same manner. Filter, wash the container and residue with 30 mL of chloroform, evaporate the combined extracts to dryness, dissolve the residue in methanol, and transfer to a 25 mL volumetric flask, dilute to volume with methanol, and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 30 °C
- Mobile phase: methanol-water (84:16)
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Diosgenin	1.289	5.722	59.25	357.9	20821	1.05

# Chuanxing Chantiao Pills (*Chuanxing Chantiao Wan*)

川芎茶调丸

## Sample source

Commercially available Chuanxing Chantiao pills

## Chemical reference substances

Ferulic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110773-9910)

## Preparation of test solution

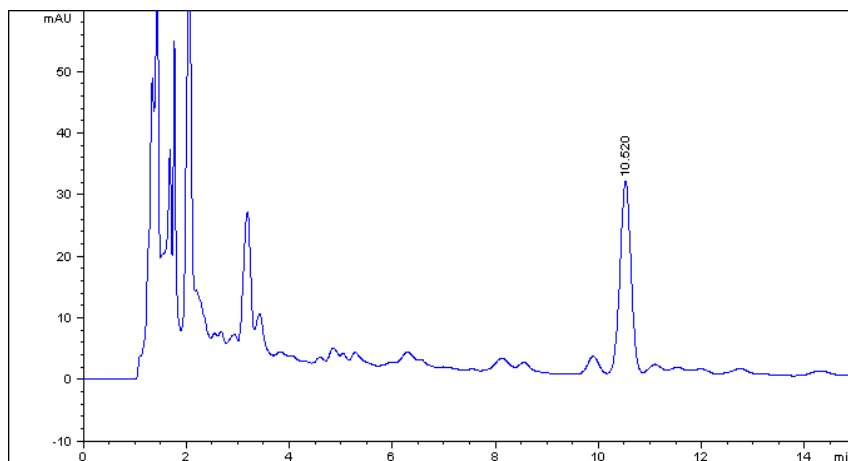
Grind a quantity of the pills to a fine powder and mix well. Accurately weigh 0.5 g of the powder, accurately add 20 mL of a mixture of 45 % ethanol and glacial acetic acid (20:1), weigh, heat under reflux for 1 hour, allow to cool, and weigh again. Replenish the lost weight with the above solution, mix thoroughly, centrifuge, and use the supernatant liquid as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 35 °C
- Mobile phase: methanol-2 % glacial acetic acid solution (25:75)
- Detector wavelength: 323 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ferulic acid	6.013	10.52	30.97	452.4	11932	0.99

# Manyprickle Acanthopanax (*Radix et Rhizoma seu Caulis*)

刺五加

## Sample source

Commercially available Manyprickle Acanthopanax

## Chemical reference substances

Syringoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111574-200201)

## Preparation of test solution

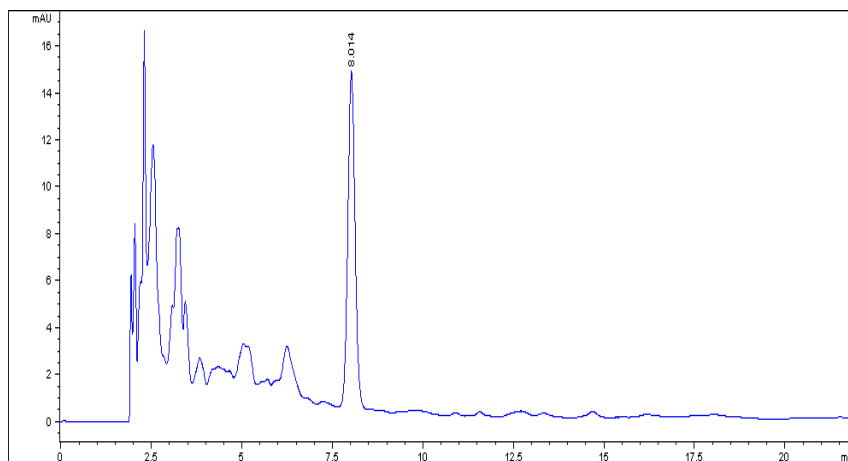
Accurately weigh 2 g of the powder in a stoppered conical flask, accurately add 25 mL of methanol, and weigh. Treat ultrasonically for 30 minutes, cool and weigh again, replenish the lost solvent with methanol and mix well, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 30 °C
- Mobile phase: methanol-water (24:76)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Syringoside	2.206	8.014	14.34	198.4	7984	1.05

# Manyprickle Acanthopanax Extract (*Extractum Acanthopanax Senticosi*) – 刺五加浸膏

## Sample source

Commercially available Radix Acanthopanax Senticosi.

## Chemical reference substances

Syringoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111574-200201)

## Preparation of test solution

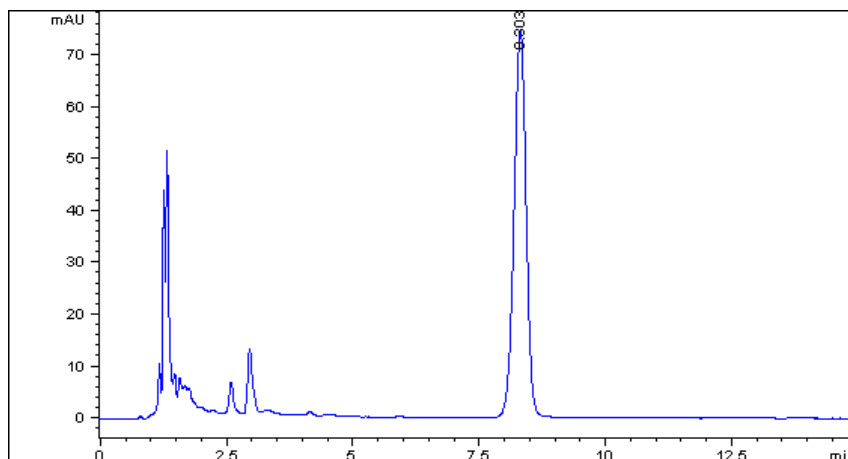
Grind 500 g to a coarse power, decoct twice with 5000 mL water, 3 hours for each time. Combine the decoctions, filter, and concentrate the filtrate to 25 g of extract. Accurately weigh 0.2 g in a 25 mL volumetric flask, dissolve in methanol and add to volume, shake well and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (20:80)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Syringoside	4.535	8.303	74.60	1238.3	5951	0.95



# Manyprickle Acanthopanax Tablets (*Tabllea Acanthopanax Senticosi*) – 刺五加片

## Sample source

Commercially available Manyprickle Acanthopanax Tablets

## Chemical reference substances

Syringoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111574-200201)

## Preparation of test solution

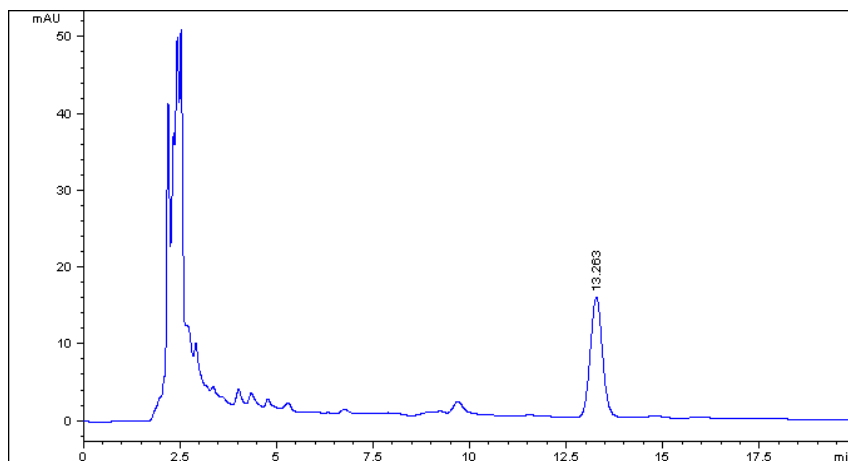
Remove sugar coating of 10 tablets and grind to a fine powder. Accurately weigh 0.48 g in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 10 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (20:80)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min
- Injection volume: 3 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Syringoside	4.305	13.263	15.59	335.7	8817	1.05

# Rhubarb (*Radix et Rhizoma Rhei*) – 大黃

## Sample source

Commercially available Rhubarb

## Chemical reference substances

1. Emodin, 2. Chrysophanol, 3. Rhein, 4. Aloe-emodin, 5. Physcion (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

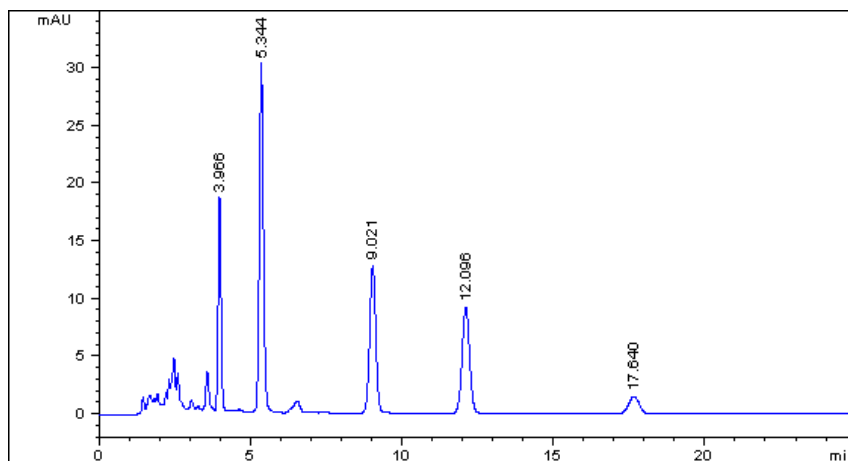
Accurately weigh 0.15 g of the powder in a stoppered conical flask, accurately add 25 mL of methanol and weigh. Heat under reflux on a water bath for 1 hour, cool, weigh again, replenish the lost solvent with methanol, mix well and filter. Accurately measure 5 mL of successive filtrate in a flask, discard the solvent, add 10 mL of 8 % solution of hydrochloric acid, treat ultrasonically for 2 minutes, and add 10 mL of chloroform. Heat under reflux for 1 hour, allow to cool, transfer to a separating funnel, wash the flask with a small quantity of chloroform and combine the washings in the separating funnel. Separate the chloroform layer, extract the acid solution again with three 10 mL quantities of chloroform, combine the chloroform extracts and evaporate the chloroform in vacuum to dryness. Dissolve the residue in methanol and transfer to a 10 mL volumetric flask, dilute with methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.6 % phosphoric acid (75:25)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	5.014	9.021	12.78	177.8	10115	1.02
Chrysophanol	7.064	12.096	9.23	158.8	11586	1.01
Rhein	2.563	5.344	30.28	281.2	8174	1.09
Aloe-emodin	1.644	3.966	18.45	123.5	8387	1.06
Physcion	10.76	17.64	1.49	37.0	11579	1.00

# Rhubarb Liquid Extract (*Extractum Rhei Liquidom*) – 大黄流浸膏

## Sample source

Commercially available Radix et Rhizoma Rhei

## Chemical reference substances

1. Emodin, 2. Chrysophanol  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 0796-200309, 2. Chrysophanol)

## Preparation of test solution

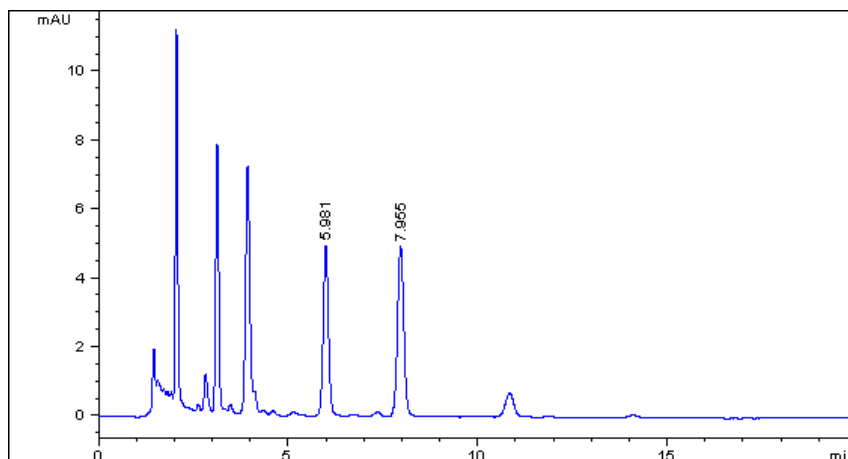
Soak 500 g of the coarse powder in 60 % ethanol for 24 hours and slowly percolate at about 1-3 mL per minute. Reserve 425 mL of the initial percolate and continue to percolate until the percolate becomes pale in color. Concentrate the successive percolate to a thick extract, mix well with the initial percolate and dilute with 60 % ethanol to give a volume of 500 mL. Allow to stand until the fluid becomes clear and filter.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1 % phosphoric acid (80:20)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
emodin	2.987	5.981	4.91	46.5	9559	1.04
chrysophanol	4.303	7.955	4.92	56.6	11275	1.03

# Dahuang Zhechong Pills (*Dahuang Zhechong Wan*) – 大黄蟪虫丸

## Sample source

Commercially available Dahuang Zhechong Pills

## Chemical reference substances

Emodin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0756-200210)

## Preparation of test solution

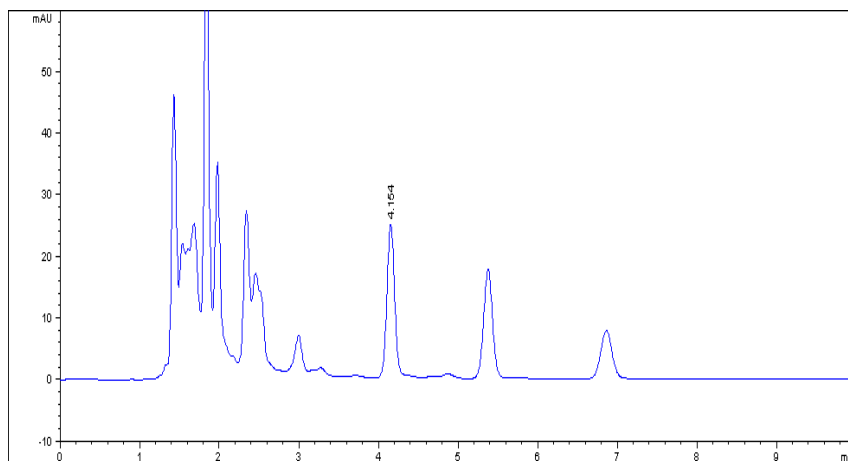
Cut a quantity of pills into pieces and mix well, take a quantity of the pieces, accurately weigh, grind well with an equal quantity of kieselguhr and mix well. Accurately weigh 4 g of the powder in a stoppered conical flask, accurately add 25 mL of methanol, weigh, heat under reflux on a water bath for 1 hour, and allow to cool, weigh again and replenish the lost weight with methanol, mix well, and filter. Accurately measure 5 mL of the successive filtrate in a conical flask, discard the solvent, add 20 mL of 2.5 mol/L sulfuric acid solution, treat ultrasonically for 10 minutes, and heat under reflux for 1 hour, and cool immediately, transfer to a separator. Extract with three 25-mL quantities of ether, combine the ether extracts, wash with 15 mL of water, combine the ether extracts, wash with 15 mL of water, discard the washings, and pass through a funnel packed with anhydrous sodium sulfate. Wash the filter and the container with a little quantity of ether, combine the washings with the filtrate, evaporate to dryness at a low temperature. Dissolve the residue with a quantity of methanol in a 25 mL volumetric flask, dilute with methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-phosphoric acid (85:15:0.05)
- Detector wavelength: 289 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	2.462	4.154	24.82	165.8	9071	1.05

# Dyers Woad Leaf (*Folium Isatidis*) – 大青叶

## Sample source

Commercially available Dyers Woad Leaf

## Chemical reference substances

Indirubin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 717-200204)

## Preparation of test solution

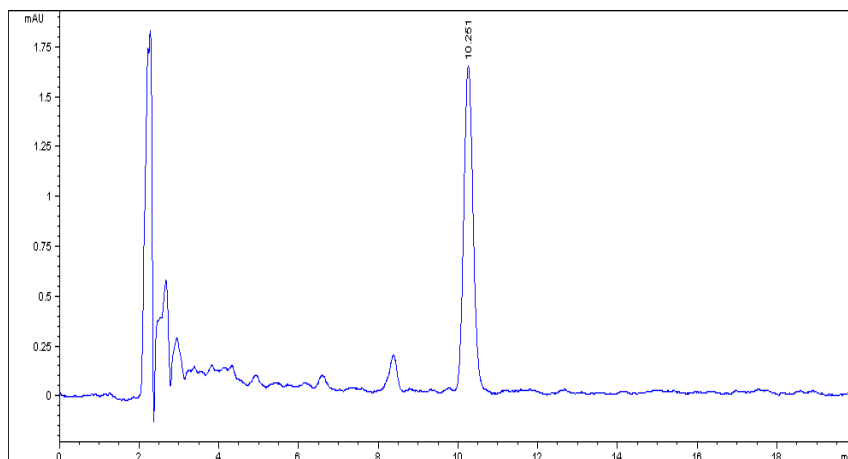
Accurately weigh 0.25 g of the fine powder in a Soxhlet extractor, add an appropriate quantity of chloroform to extract for 15 hours, heat under reflux until the extract is colorless. Evaporate the solvent to dryness, dissolve the residue in methanol and transfer to a 100 mL volumetric flask, add methanol to volume, mix well, filter, and use the filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX Extend C18, 4.6×250 mm, 5 µm (770450-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (72:28)
- Detector wavelength: 289 nm
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Indirubin	3.100	10.251	1.62	25.9	9503	1.08

# Danshen Root (*Radix et Rhizoma Salviae Miltiorrhizae*) – 丹参

## Sample source

Commercially available Danshen Root

## Chemical reference substances

Tanshinone IIA (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0766-200010)

## Preparation of test solution

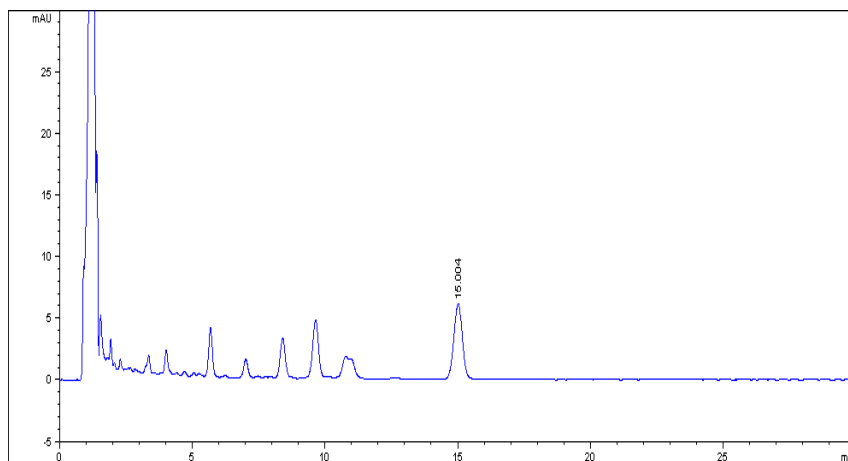
Accurately weigh 0.3 g of the powder in a stoppered conical flask. Accurately add 50 mL of methanol and weigh. Heat under reflux for 1 hour, allow to cool and weigh again, replenish the lost solvent with methanol, mix well and filter. Use the successive filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (75:25)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
tanshinone IIA	11.503	15.004	6.07	133.3	10789	0.99

# Danshen Root (*Radix et Rhizoma Salviae Miltiorrhizae*) – 丹参

## Sample source

Commercially available Danshen Root

## Chemical reference substances

Salvianolic acid B (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 11562-200302)

## Preparation of test solution

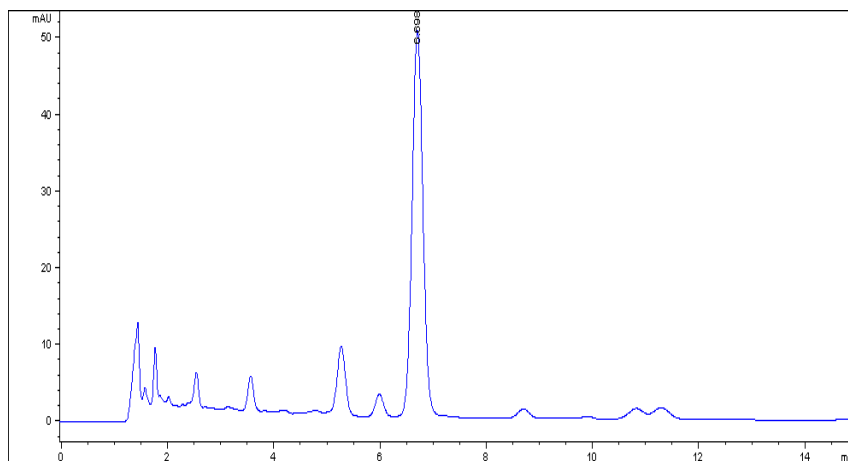
Accurately weigh 0.2 g of the powder in a stoppered conical flask, accurately add 50 mL of 75 % methanol and weigh. Heat under reflux for 1 hour, allow to cool and weigh again, replenish the lost solvent with 75 % methanol, mix well and filter. Use the successive filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-acetonitrile-formic acid-water (30:10:1:59)
- Detector wavelength: 286 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Salvianolic acid B	4.582	6.698	50.27	706.1	5349	1.03

# Danle Capsules (*Danle Jiaonang*) – 胆乐胶囊

## Sample source

Commercially available Danle Capsules

## Chemical reference substances

hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110721-200211)

## Preparation of test solution

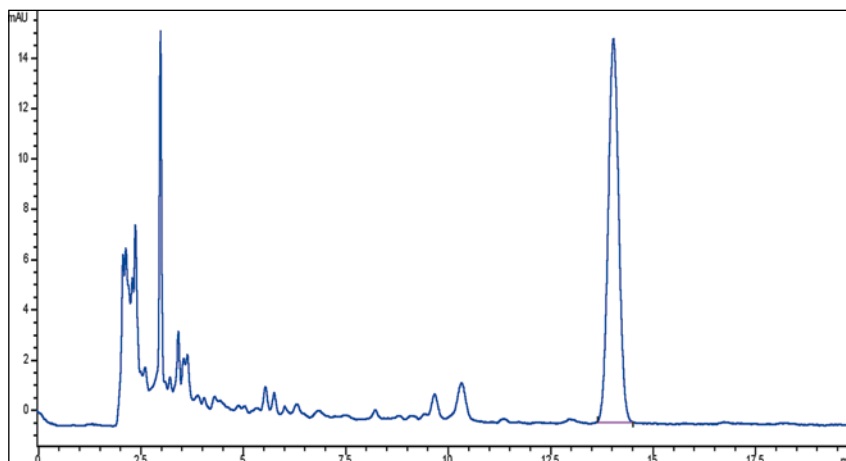
Grind a quantity of the capsule contents to a fine powder and mix well. Accurately weigh 0.3 g of the powder in a Soxhlet extractor, add a quantity of methanol, heat under reflux on a water bath for 6 hours. Transfer the extract to a 100 mL volumetric flask, dilute with methanol to volume and mix well. Filter through a millipore membrane (0.45 µm), and use the filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.2 % phosphoric acid (20:80)
- Detector wavelength: 284 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide	3.295	5.154	46.33	444.1	6790	0.99



# Danning Tablets (*Danning Pian*) – 胆宁片

## Sample source

Commercially available Danning Tablets

## Chemical reference substances

1. Emodin, 2. Chrysophanol  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110756-200210, 2. 110796-200309)

## Preparation of test solution

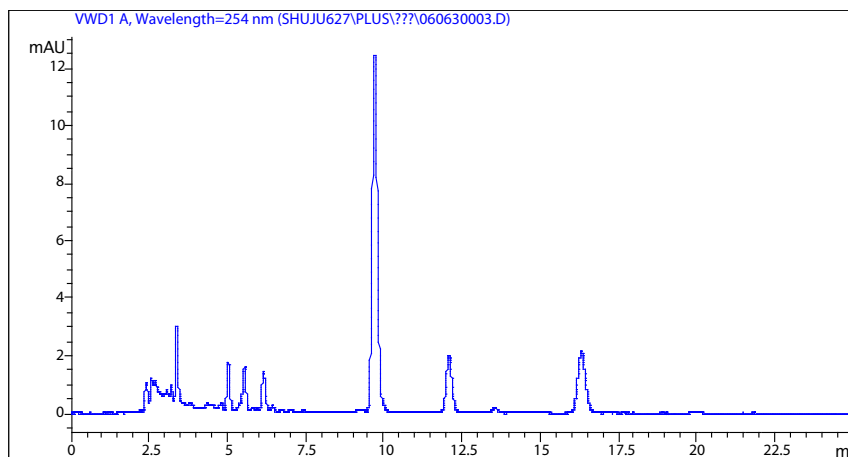
Remove the coating of 10 tablets, grind to a fine powder, accurately weigh 0.35 g of the powder and place in a round-bottomed flask. Add 10 mL 30% solution of sulfuric acid, and heat under reflux with successive 30 mL, 20 mL, 20 mL of chloroform for 2 hours, 30 minutes and 30 minutes respectively. Combine the chloroform solution and wash with a quantity of water, transfer the chloroform solution to a 100 mL volumetric flask, dilute with chloroform to volume, mix thoroughly. Accurately measure 3 mL of the chloroform solution in a 10 mL volumetric flask, evaporate to dryness, dissolve the residue in about 9 mL of methanol, treat ultrasonically for 3 minutes, dilute with methanol to volume, mix thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Eclipse Plus C18, 4.6×250mm, 5µm (959990-902)
- Column temperature: 30 °C
- Mobile phase: methanol-0.1 % phosphoric acid (80:20)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	2.886	9.715	12.29	139.3	17128	1.07
Chrysophanol	3.833	12.082	1.90	27.7	21457	1.04

# Chinese Angelica (*Radix Angelicae Sinensis*) – 当归

## Sample source

Commercially available Chinese Angelica

## Chemical reference substances

Ferulic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110773-9910)

## Preparation of test solution

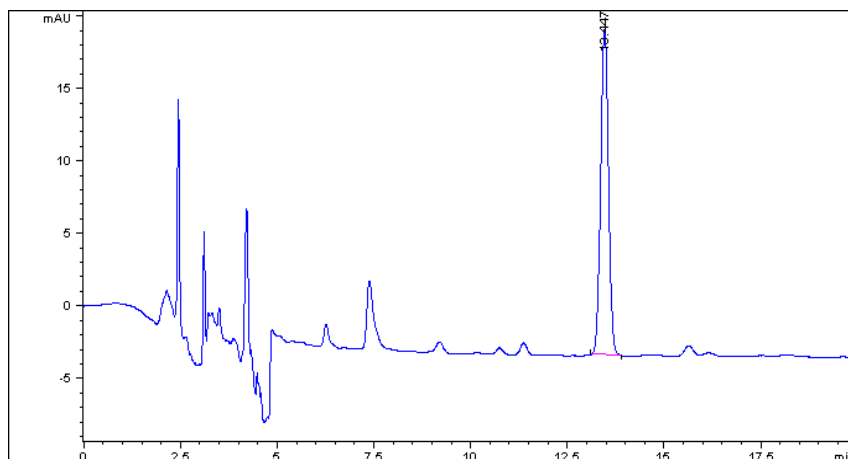
Accurately weigh 0.2 g of the powder in a stoppered conical flask. Accurately add 20 mL of 70 % methanol and weigh. Heat under reflux for 30 minutes, cool, weigh again, replenish the lost weight with 70 % methanol, mix well and allow to stand. Filter the supernatant through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.085 % phosphoric acid (17:83)
- Detector wavelength: 316 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ferulic acid	4.379	13.447	22.42	318.0	21120	1.01

# Shortscape Fleabane Herb (*Herba Lysimachiae*) – 灯盏细辛

## Sample source

Commercially available Shortscape Fleabane Herb (Yunnan province)

## Chemical reference substances

Scutellarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 842-200102)

## Preparation of test solution

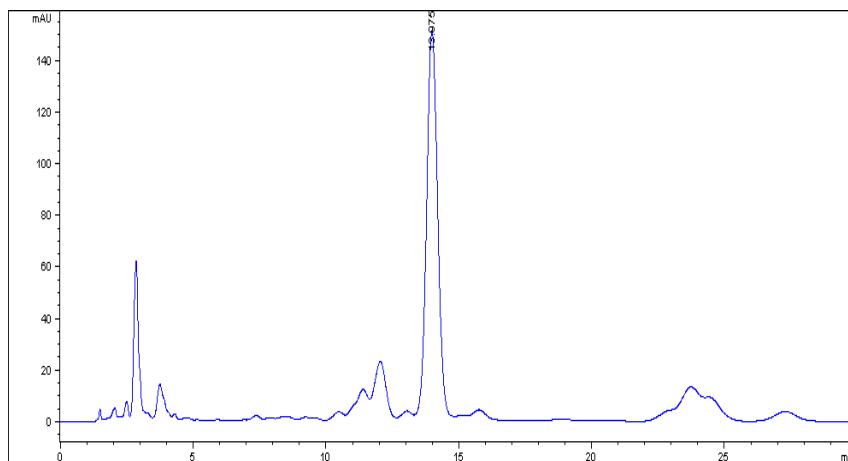
Accurately weigh 0.5 g of the powder in a Soxhlet extractor, add an appropriate quantity of chloroform, heat under reflux until the extract is colorless and discard the chloroform extract. Evaporate the solvent, transfer the residue and the filter to a stoppered conical flask, accurately add 50 mL of methanol, weigh, allow to stand for 1 hour, heat under reflux on a water bath for 1 hour, allow to cool, weigh again, and replenish the lost weight with methanol, mix well, filter. Accurately measure 25 mL of the successive filtrate, evaporate to dryness, dissolve the residue in methanol and transfer to a 10 mL volumetric flask, dilute with methanol to volume, mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1 % phosphoric acid (35:65)
- Detector wavelength: 335 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Scutellarin	8.317	13.975	149.34	4238.4	5589	1.05

# Dengzhan Xixin Injection (*Injection Herba Erigerontis*)

## 灯盏细辛注射液

### Sample source

Commercially available Dengzhan Xixin Injection Fluid

### Chemical reference substances

Scutellarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 842-200102)

### Preparation of test solution

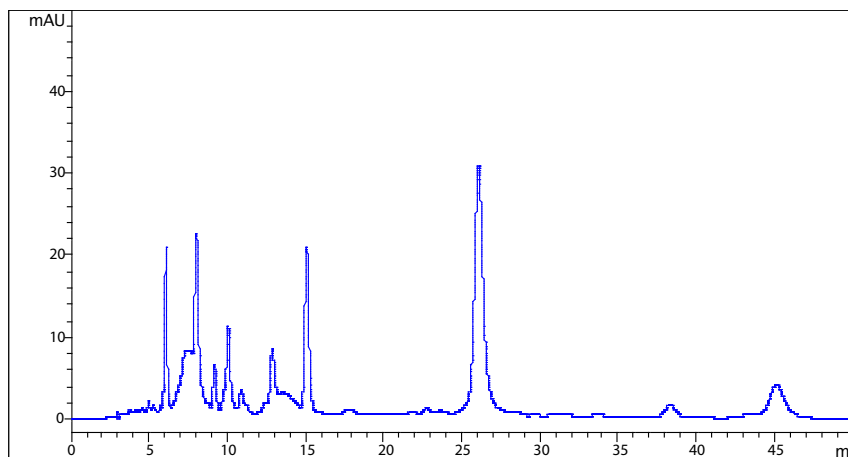
Accurately measure 2 mL of the injection fluid in a 10 mL volumetric flask, dilute with water to volume, mix well and filter. Use the filtrate as the test solution.

### Chromatographic conditions

- Column: Agilent TC-C18, 4.6×250 mm, 5 μm (518925-902)
- Column temperature: 25 °C
- Mobile phase: methanol-tetrahydrofuran-0.1 % phosphoric acid (15:13:74)
- Detector wavelength: 335 nm
- Flow rate: 1.0 mL/min

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Scutellarin	9.431	26.007	29.40	1131.2	11684	1.13

# Rehmannia Root (*Radix Rehmanniae*) – 地 黄

## Sample source

Commercially available Rehmannia Root

## Chemical reference substances

Catalpol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110808-200304)

## Preparation of test solution

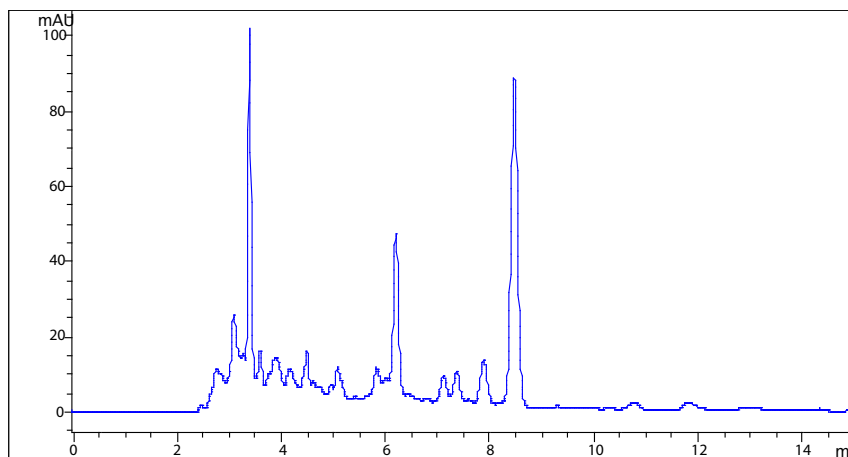
Accurately weigh 2.0 g of the powder in a round-bottom flask, accurately add 100 mL of methanol. Heat under reflux for 1.5 hours, allow to cool, filter. Collect filtrate in a 100 mL volumetric flask, wash several times with 15 mL of methanol, combine the washings in the volumetric flask, add methanol to the volume and mix well. Accurately measure 20 mL of the filtrate and evaporate to almost dryness. Dissolve the residue in the mobile phase, transfer to a 10 mL volumetric flask, dilute to volume with the same solvent and mix well.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6×150 mm, 5 µm (518935-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.15% phosphoric acid (1:99)
- Detector wavelength: 210 nm ±8nm
- Reference wavelength: 360 nm ±50 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Rs	n	USP T <sub>r</sub>
Catalpol	2.231	7.882	115.2	2.48	16911	0.99

# Creeping Euphorbia (*Herba Euphorbiae Humifusae*) – 地锦草

## Sample source

Commercially available Creeping Euphorbia

## Chemical reference substances

Quercetin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0081-9905)

## Preparation of test solution

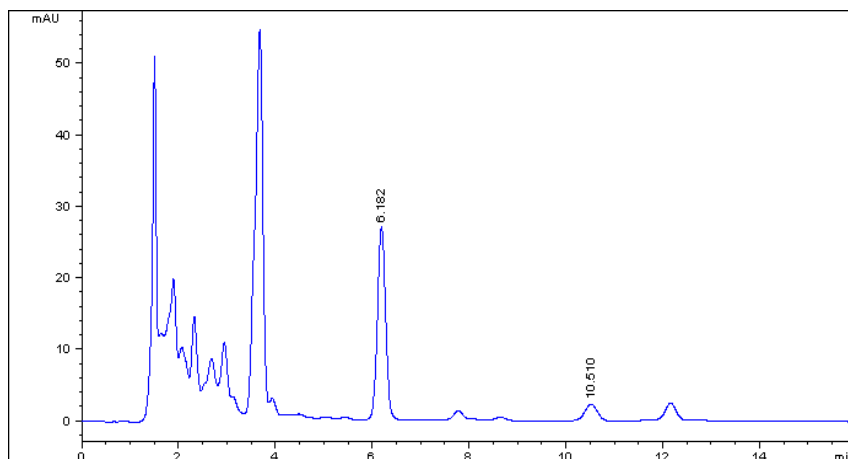
Accurately weigh 1.5 g of the powder in a stoppered conical flask. Accurately add 50 mL of 80 % methanol and weigh. Heat under reflux for 1.5 hours, cool, weigh again, replenish the lost weight with 80 % methanol, mix well and filter. Accurately measure 20 mL of the filtrate and accurately add 7 mL of 25 % hydrochloric acid to the filtrate. Heat on a water bath at 85 °C for 30 minutes and cool immediately. Transfer to a 50 mL volumetric flask, dilute with methanol to volume and mix well, filter, and use the successive filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-0.4 % phosphoric acid (50:50)
- Detector wavelength: 360 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Quercetin	3.121	6.182	26.96	317.6	6565	1.02

# Dieda Pills (*Dieda Wan*) – 跌打丸

## Sample source

Commercially available Dieda Pills

## Chemical reference substances

Dracorhodin perchlorate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110811-200203)

## Preparation of test solution

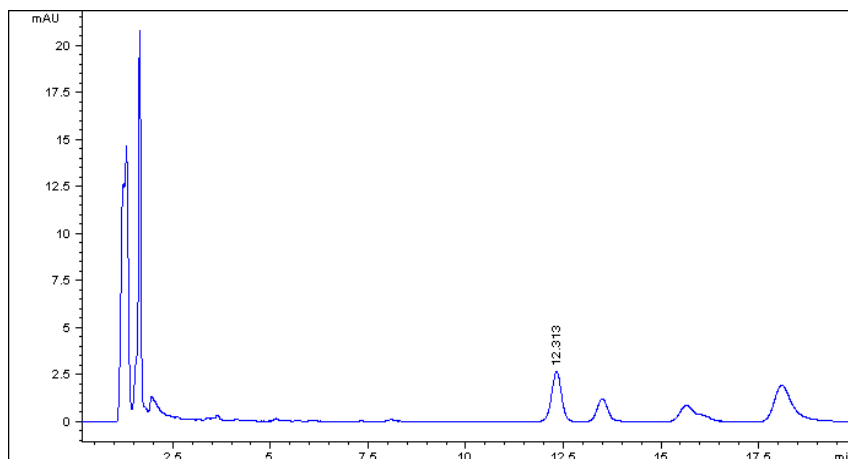
Cut a quantity of the pills into pieces and mix well, accurately weigh 0.4 g of the pieces, accurately add 5 mL of 3 % solution of phosphoric acid in methanol, weigh, heat under reflux for 30 minutes, allow to cool, weigh again and replenish the lost weight with a 3 % solution of phosphoric acid in methanol, mix well, centrifuge, filter the supernatant through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.05mol/L sodium dihydrogen phosphate (40:60)
- Detector wavelength: 440 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Dracorhodin	9.261	12.313	2.66	46.0	12005	1.00

# Obtuseleaf Erycibe Stem (*Caulis Erycibes*) – 丁公藤

## Sample source

Commercially available Obtuseleaf Erycibe Stem

## Chemical reference substances

scopoletin (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

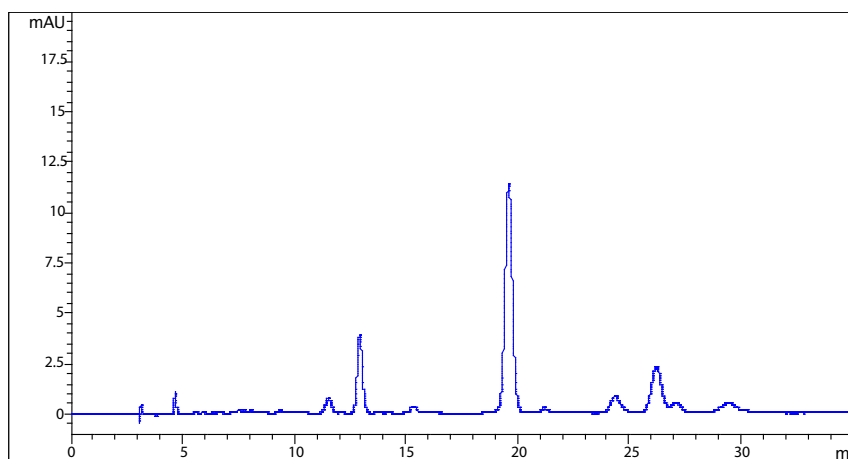
Accurately weigh 1 g of the powder in a stoppered conical flask. Accurately add 50 mL of 70% ethanol, weigh, heat on a water bath for 6 hours, allow to cool, weigh again, replenish the lost weight with 70% ethanol, mix well and filter. Accurately measure 25 mL of the filtrate to a flask, evaporate to about 1 mL, and add 10 mL of 3 mol/L hydrochloric acid, heat on a water bath for 2 hours, cool immediately. Transfer to a separating funnel, wash the flask several times with 10 mL of water, combine the washings in the separating funnel, add 2 g of sodium chloride, extract with five 15 mL quantities of chloroform, combine the chloroform extracts, add 2 g of anhydrous sodium sulfate, stir well and filter, wash the separating funnel with a small quantity of chloroform, filter, combine the filtrates and evaporate to almost dryness below 70 °C, immediately dissolve the residue in methanol, transfer to a 10 mL volumetric flask, dilute to volume and mix well.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6×250 mm, 5 µm (518925-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid (30:70:0.14)
- Detector wavelength: 298 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Scopoletin	19.603	11.30	260.4	17195	1.002



# Dingkun Pills (*Dingkun Dan*) – 定坤丹

## Sample source

Commercially available Dingkun Pills

## Chemical reference substances

Ginsenoside Rg1 (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110703-200322)

## Preparation of test solution

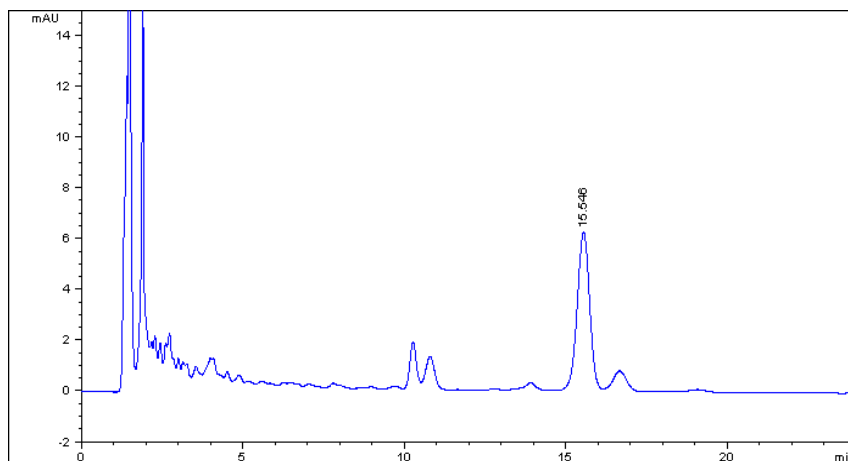
Cut a quantity of the pills into pieces and mix well, accurately weigh 2 g of the pills, add 2 g of kieselguhr, stir well. Place in a Soxhlet extractor, add 100 mL of methanol, heat under reflux until the extract becomes almost colorless, and evaporate to dryness. Dissolve the residue in 30 mL of water, extract with three 20-mL quantity of chloroform, discard the chloroform extract, extract with four 30 mL quantities of n-butanol saturated with water, combine the n-butanol extracts, wash with three 30 mL quantities of 1 % sodium hydroxide solution, and wash with water saturated with n-butanol to neutral. Evaporate the n-butanol to dryness, dissolve the residue with methanol in a 10 mL volumetric flask, dilute with methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.05 % phosphoric acid (21:79)
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ginsenoside Rg1	9.364	15.546	6.23	166.4	8056	0.96

# Pubescent Angelica Root (*Radix Angelicae Pubescentis*) – 独活

## Sample source

Commercially available Double-teeth Pubescent Angelica Root (Sichuan province)

## Chemical reference substances

Osthole (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110822-200305)

## Preparation of test solution

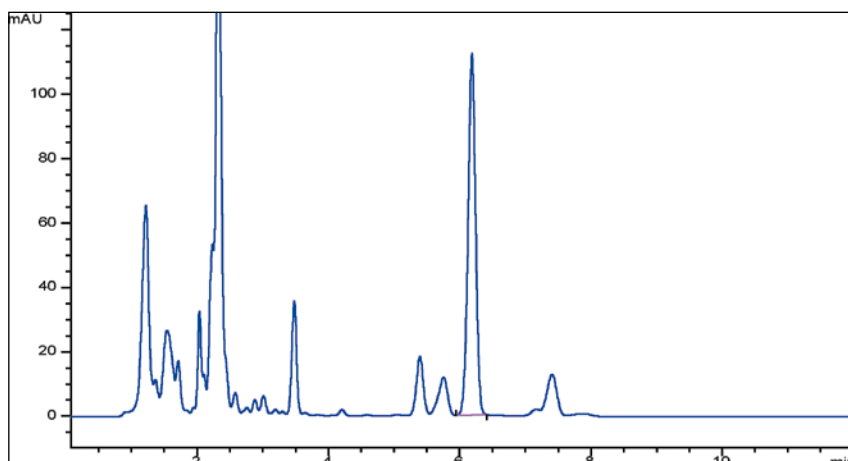
Accurately weigh 0.06 g of the powder in a 10 mL volumetric flask, accurately add 10 mL of methanol, and weigh. Treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost solvent with methanol and mix well. Filter through millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (60:40)
- Detector wavelength: 322 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Osthole	4.156	6.187	112.38	908.7	13845	0.97

# Duyiwei Capsules (*Capsule Radix Lamio-phlomidies Ratatae*)

## 独一味胶囊

### Sample source

Commercially available Duyiwei Capsules

### Chemical reference substances

luteolin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111520-200201)

### Preparation of test solution

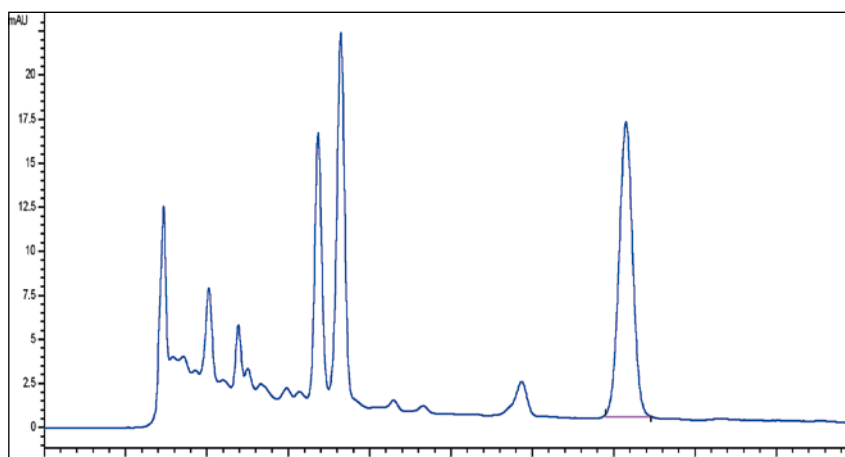
Accurately weigh 0.06 g of the powder contents in a 10 mL volumetric flask, add 20 mL of 2.5 mol/L solution of hydrochloric acid in methanol, treat ultrasonically for 30 minutes, allow to cool. Dilute with a 2.5 mol/L solution of hydrochloric acid in methanol to volume, mix well and filter. Accurately transfer 4 mL of the filtrate to a 10 mL round-bottomed flask, heat on a water bath at 90 °C for 30 minutes and allow to cool. Transfer to a 10 mL volumetric flask, dilute with methanol to volume, mix well, filter, and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-0.4 % phosphoric acid solution (50:50)
- Detector wavelength: 350 nm
- Flow rate: 1.0 mL/min

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Luteolin	4.959	7.151	16.74	195.6	8946	1.00

# Chinese Clinopodium Granules (*Granules Clinopodii*)

## 断血流颗粒

### Sample source

Commercially available Chinese Clinopodium Granules

### Chemical reference substances

Buddlejasaponin IVb (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110782-200301)

### Preparation of test solution

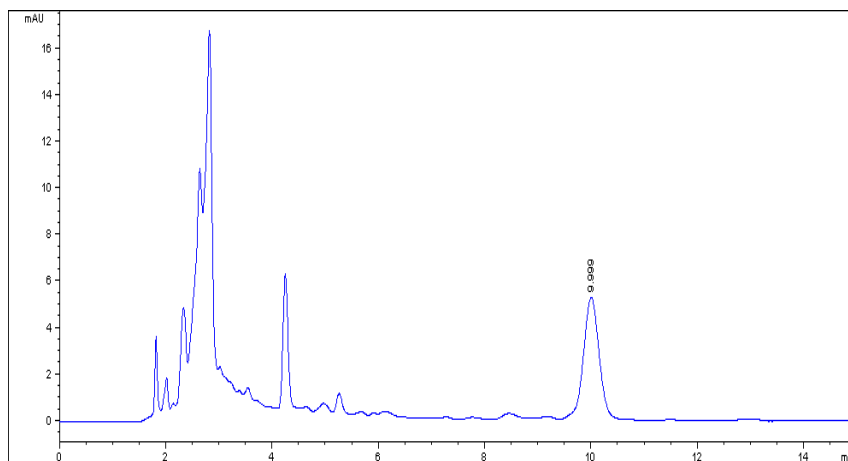
Grind the granules to a fine powder. Accurately weigh 0.5 g of the powder, add 30 mL of methanol, treat ultrasonically for 15 minutes and filter. Add 30 mL of methanol to the residue, treat ultrasonically for 15 minutes and filter. Combine the filtrates, evaporate to dryness, dissolve the residue in 30 mL of water, transfer to a separator funnel, extract with four 20 mL quantities of n-butanol saturated with water. Combine the n-butanol extract and wash with 30 mL of ammonia saturated with n-butanol and wash successively with two 30 mL quantities of water saturated with n-butanol. Separate the n-butanol extract, evaporate to dryness, dissolve the residue in methanol, and transfer to a 50 mL volumetric flask. Dilute with methanol to volume, mix well and filter. Use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (78:22)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Buddlejasaponin IVb	3.00	9.999	5.23	106.5	5925	0.98

# Chinese Clinopodium Tablets (*Tabellae Clinopodii*) – 断血流片

## Sample source

Commercially available Chinese Clinopodium Tablets

## Chemical reference substances

buddlejasaponin IVb (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110782-200301)

## Preparation of test solution

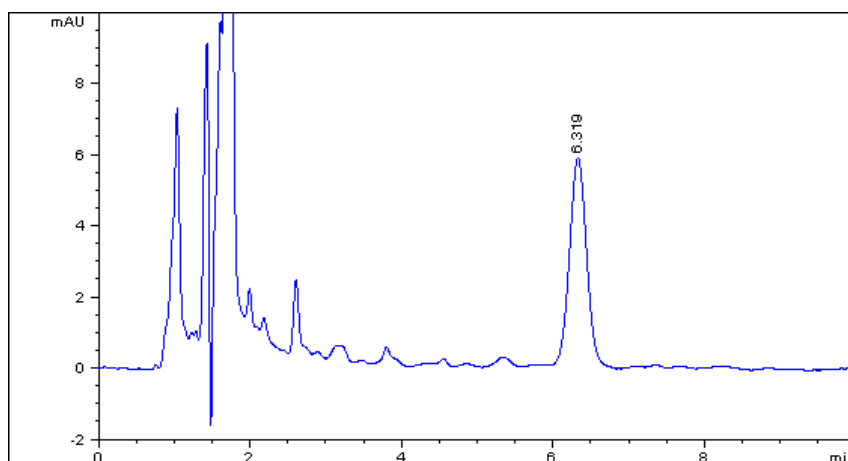
Remove the coating of 20 tablets and grind to a fine powder. Accurately weigh 0.3 g of the powder in a stoppered conical flask, accurately add 20 mL of methanol, treat ultrasonically for 15 minutes and filter. Accurately add 20 mL of methanol, and treat ultrasonically for 15 minutes again, filter. Combine the filtrates, evaporate to dryness, dissolve the residue in 30 mL of water, and transfer to a separating funnel, extract with four 20 mL quantities of n-butanol saturated with water, combine the n-butanol extracts, wash with 30 mL of ammonia saturated with n-butanol, wash with two 30 mL quantities of water saturated with n-butanol, Evaporate n-butanol solution to dryness, dissolve the residue in methanol, and transfer to a 100 mL volumetric flask, add methanol to volume, mix well and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (77:23)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Buddlejasaponin IVb	3.213	6.319	5.85	91.6	3841	1.03

# Erchen Pills (*Erchen Wan*) – 二陈丸

## Sample source

Commercially available Erchen Pills

## Chemical reference substances

hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0721-200211)

## Preparation of test solution

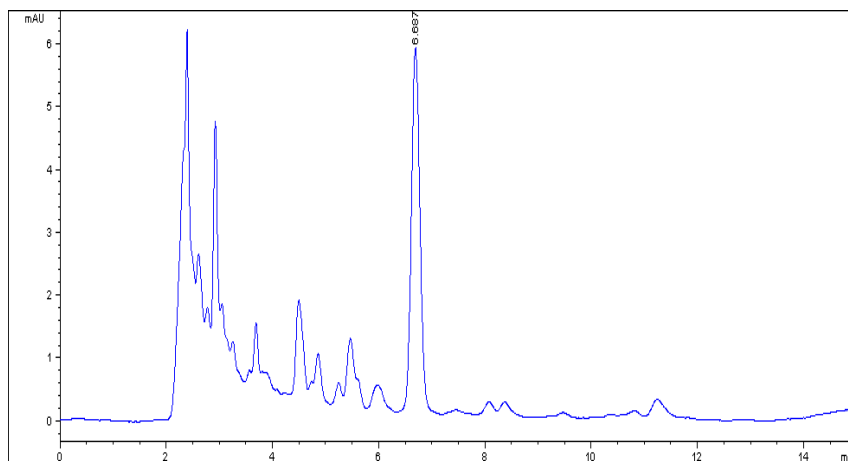
Grind a quantity of the pills to a powder, accurately weigh 0.5 g of the powder. Place in a Soxhlet extractor, add a quantity of petroleum ether (60-90 °C), heat under reflux for 2 hours, discard the petroleum ether, evaporate the residue to dryness, add a quantity of methanol, heat under reflux until the extract becomes almost colorless (about 7 hours), allow to cool. Transfer the methanol extract to a 50 mL volumetric flask, wash the container with small quantities of methanol in portions, combine the washings in the same volumetric flask, dilute to volume and shake well. Accurately measure 3 mL in a 10 mL volumetric flask, dilute to volume with methanol, mix well for use.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 40 °C
- Mobile phase: methanol-1 % glacial acetic acid (39:61)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	1.675	6.687	5.78	63.9	8584	1.05

# Erkangning Syrup (*Erkangning Tangjiang*) – 儿康宁糖浆

## Sample source

Commercially available Erkangning Syrup

## Chemical reference substances

2,3,5,4'-tetrahydroxystilbene-2-O- $\beta$ -D-glucoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0844-200003)

## Preparation of test solution

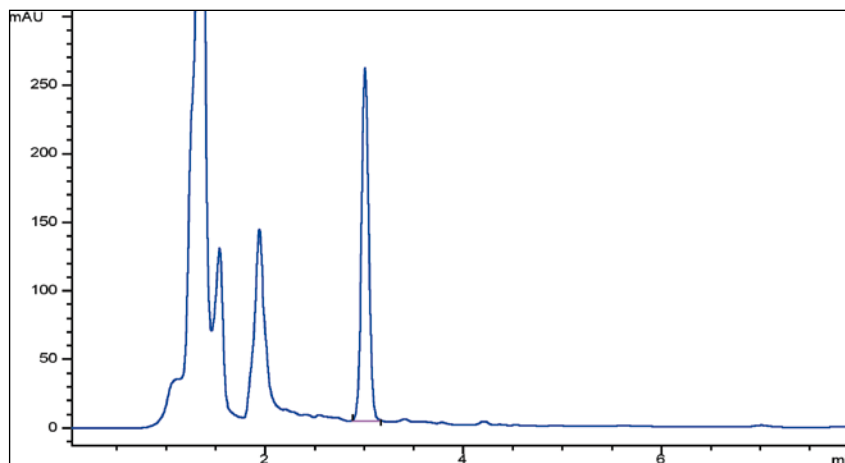
Accurately measure 2 ml, in a 10 ml amber volumetric flask, dilute to volume with dilute ethanol, mix well, centrifuge, filter the supernatant through a millipore film (0.45  $\mu$ m) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu$ m (883975-902)
- Column temperature: 35  $^{\circ}$ C
- Mobile phase: acetonitrile-water (24:76)
- Detector wavelength: 320 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu$ L

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
2,3,5,4'-tetrahydroxystilbene-2-O- $\beta$ -D-glucoside	1.507	3.008	257.4	1302.6	8524	1.03

# Ertong Qingfei Pills (*Ertong Qingfei Wan*) – 儿童清肺丸

## Sample source

Commercially available Ertong Qingfei Pills

## Chemical reference substances

baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

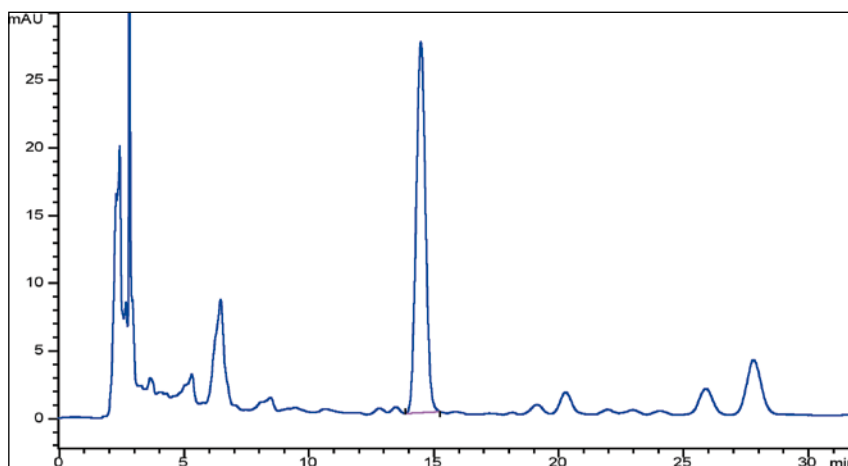
Cut a quantity of the pills into pieces, accurately weigh 1 g of the pieces, grind well with 0.5 g of kieselguhr and mix well. Put in a conical flask, add 40 ml of 70 % ethanol, heat under reflux on a water bath for 2 hours, allow to cool, filter, transfer the filtrate to a 100 ml volumetric flask, wash the container and residue with a small quantity of 70 % ethanol in portions, combine the washings in the same volumetric flask, dilute with 70 % ethanol to volume and shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-0.36 % phosphoric acid (46:54)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	4.791	14.477	27.42	713.0	7138	1.04



# Curcuma Oils (*Oleum Curcumae*) – 莪术油

## Sample source

Commercially available Curcuma Oils

## Chemical reference substances

Germacrone (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111665-200401)

## Preparation of test solution

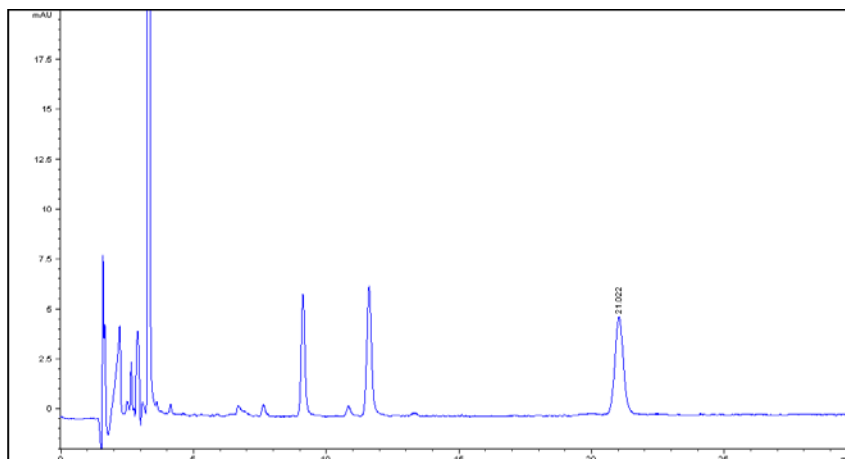
Accurately weigh 0.1 g of the oil in a 50 ml volumetric flask, add ethanol to volume and shake well. Accurately measure 2 ml into a 25 ml volumetric flask, add the mobile phase to volume, shake well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB CN 4.6×250,5µm (990967-905)
- Column temperature: 50 °C
- Mobile phase: acetonitrile-water (30:70)
- Detector wavelength: 210 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Germacrone	7.409	21.022	4.88	109.5	21178	1.06

# Fourstamen Stephania Root (*Radix Stephaniae Tetrandrae*) – 防己

## Sample source

Commercially available Fourstamen Stephania Root

## Chemical reference substances

1. Fanchinoline, 2. Tetrandrine  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110793-200003, 2. 110711-200205)

## Preparation of test solution

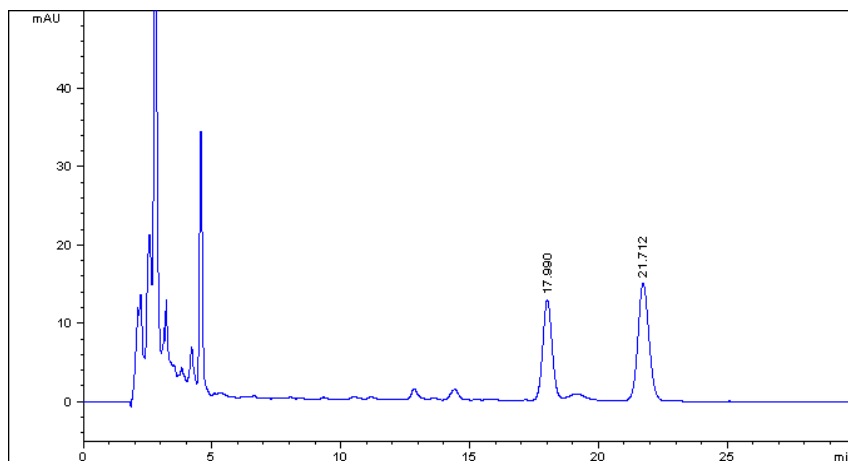
Accurately weigh 0.5 g of the powder, accurately add 25 ml of a 2 % solution of hydrochloric acid in methanol, and weigh. Heat under reflux for 30 minutes, allow to cool and weigh again, replenish the lost weight with a 2 % solution of hydrochloric acid in methanol and filter. Accurately measure 5 ml of the filtrate in a 10 ml volumetric flask, dilute with the mobile phase to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18  
4.6×250 mm, 5 µm (880975-902)
- Column temperature: 30 °C
- Mobile phase: acetonitrile-methanol-1 % sodium dodecylsulfonate (1 % glacial acetic acid) (49:23:28)
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Fanchinoline	6.196	17.99	12.85	325.6	11894	1.07
Tetrandrine	7.685	21.712	14.99	441.4	12819	1.07

# Thomson Kudzuvine Root (*Radix Puerariae Thomsonii*) – 粉葛

## Sample source

Commercially available Thomson Kudzuvine Root

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110752-200209)

## Preparation of test solution

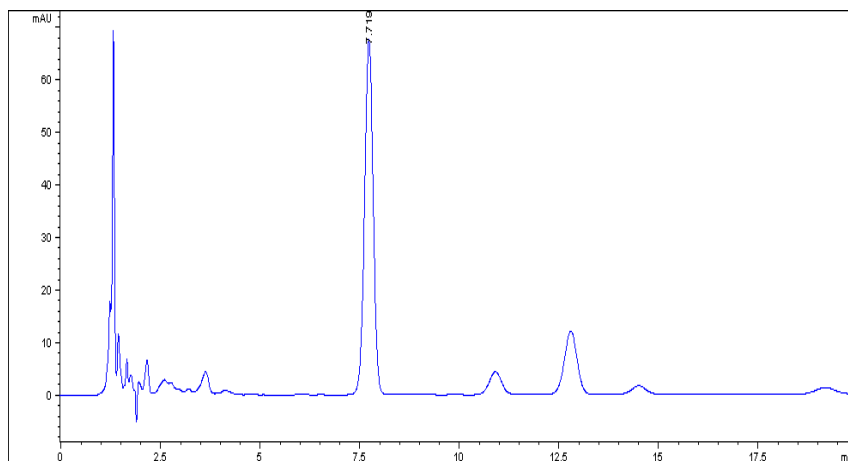
Accurately weigh 0.8 g of the powder in a conical flask, accurately add 50 ml of 30 % ethanol and weigh. Heat under reflux on a water bath for 30 minutes, allow to cool, and weigh again, replenish the lost solvent with 30 % ethanol and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (25:75)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	4.416	7.719	67.57	1016.5	6180	1.01

# Fenghan Kesou Granules (*Fenghan Kesou Keli*) – 风寒咳嗽颗粒

## Sample source

Commercially available Fenghan Kesou Granules

## Chemical reference substances

Ephedrine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

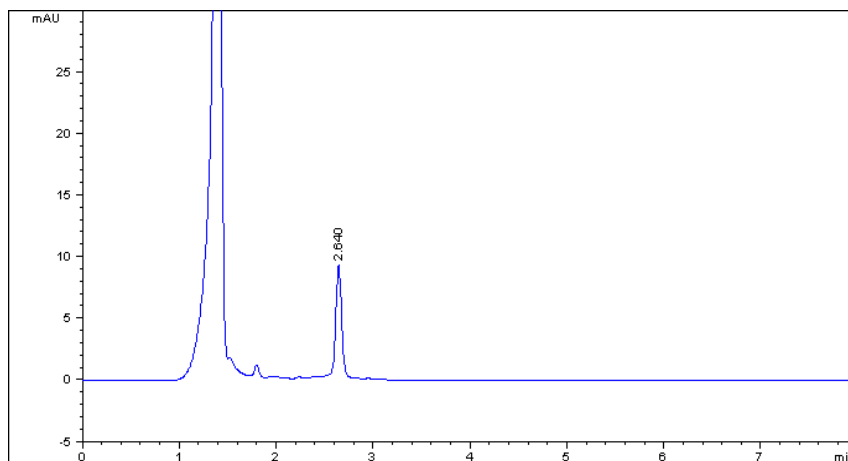
Grind a quantity of granules to a fine powder, accurately weigh 3 g of the powder in a round-bottom flask, add 120 mL of a 5 mol/L solution of sodium hydroxide, stir well, add 7.5 g of sodium chloride, treat ultrasonically for 30 minutes. Add 50 mL of water and distill, collect about 95 mL of the distillate in a 100 mL volumetric flask containing 5 mL of 0.5 mol/L hydrochloric acid, add water to volume, shake well, accurately measure 10 mL of the solution into a 25 mL volumetric flask. Add 1 mL of periodic acid solution (0.25 g/10 mL) and 2.5 mL of 0.25 mol/L sodium hydroxide, and mix well. Allow to stand for 30 minutes, add 0.5 mol/L solution of hydrochloric acid to adjust to pH 7, then add methanol to volume, mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (64:36)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ephedrine	1.2	2.640	9.00	37.4	9697	1.02

# Fubao Granules (*Fubao Keli*) – 妇宝颗粒

## Sample source

Commercially available Fubao Granules

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

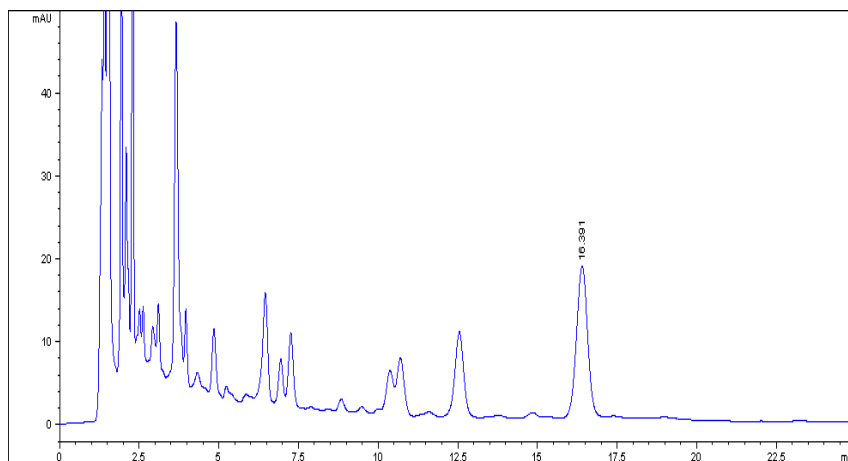
Grind a quantity of the granules to a fine powder, accurately weigh 1 g of the powder in a stoppered conical flask. Accurately add 20 mL of 50 % methanol, shake to dissolve, allow to stand overnight, shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.01mol/L phosphoric acid (11:89)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	9.927	16.391	18.30	444.2	10679	1.01

# Compound Danshen Dripping Pills (*Fufang Danshen Diwan*)

## 复方丹参滴丸

### Sample source

Commercially available Compound Danshen Dripping Pills

### Chemical reference substances

Sodium tanshinol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 855-200102)

### Preparation of test solution

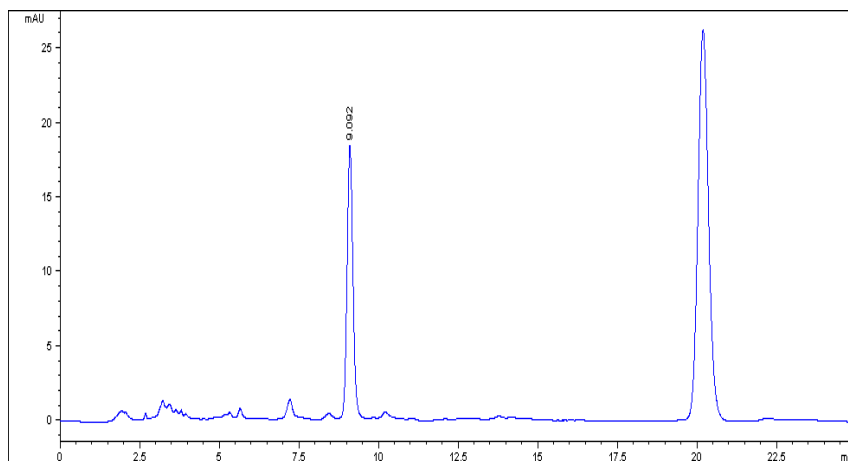
Accurately weigh 12 pills in a 25 mL volumetric flask. Break the coatings of the coated-film pills with a mortar, wash the mortar with a quantity of methanol, combine the washings in the same volumetric flask, add methanol to a volume of about 15 mL. Treat ultrasonically for 10 minutes, allow to reach room temperature. Dilute with methanol to volume, mix well, centrifuge for 5 minutes and use the supernatant as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Column temperature: 30 °C
- Mobile phase: methanol-1% glacial acetic acid (3:97)
- Detector wavelength: 281 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Tanshinol	2.637	9.092	18.26	229.6	12462	1.09

# Fufang Guazijin Granules (*Fufang Guazijin Keli*) – 复方瓜子金颗粒

## Sample source

Commercially available Fufang Guazijin Granules

## Chemical reference substances

Aesculetin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110741-200105)

## Preparation of test solution

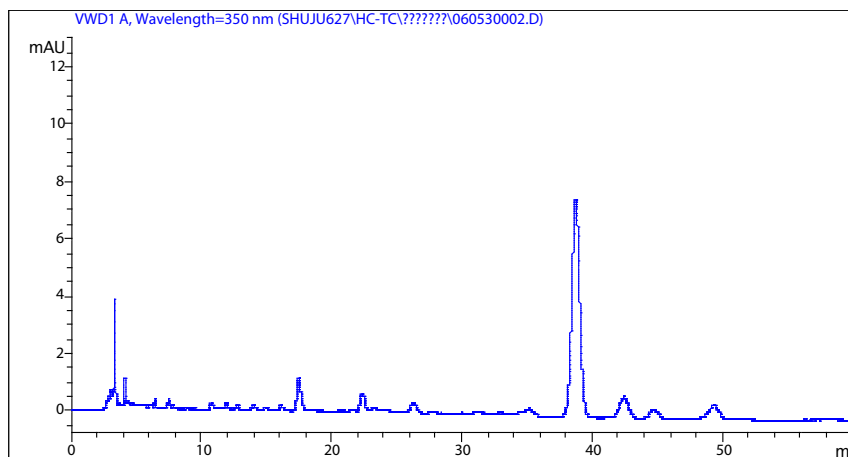
Grind the granules to a fine powder, accurately weigh 4 g in a stoppered conical flask, accurately add 25 mL of methanol, and weigh. Heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, and mix thoroughly. Filter, accurately measure 5 mL of the filtrate in a 10 mL volumetric flask, dilute with water to volume, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6×250 mm, 5 μm (518925-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.1% phosphoric acid (7:93)
- Detector wavelength: 350 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Rs	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Aesculetin	3.34	38.752	7.53	312.1	20271	0.995

# Compound Berberine Hydrochloride Tablets (*Fufang Huangliangsu Pian*) – 艾附暖宫丸

## Sample source

Commercially available Compound Berberine Hydrochloride Tablets

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 736-200220)

## Preparation of test solution

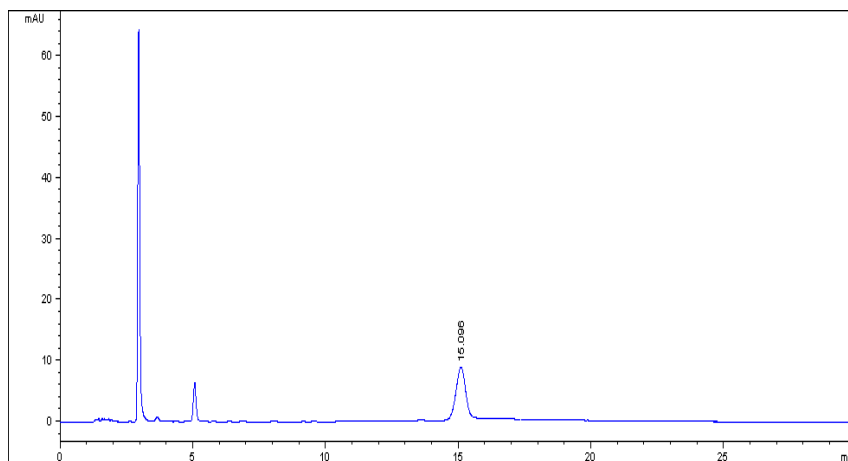
Accurately weigh 20 tablets, remove the coating and grind to a fine power and mix well. Accurately weigh 0.5 g in a stoppered conical flask, accurately add 25 mL of dilute ethanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to reach room temperature and weigh again, replenish the lost weight with dilute ethanol, shake thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.033 % potassium dihydrogen phosphate (11:89)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	9.064	15.096	8.49	209.6	8809	1.03



# Compound Berberine Hydrochloride Tablets (*Fufang Huangliang-su Pian*) – 复方黄连素片

## Sample source

Commercially available Compound Berberine Hydrochloride Tablets

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

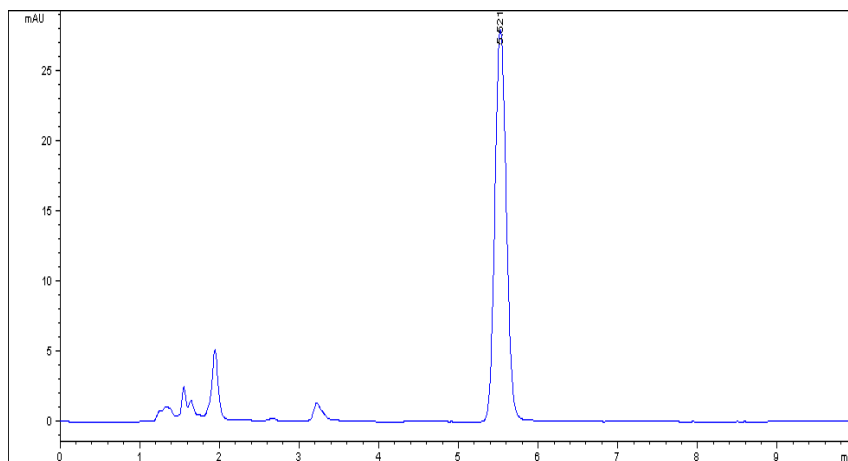
Accurately weigh 20 tablets, remove the coating, grind to a fine power and mix well. Accurately weigh 0.2 g in a 50 mL beaker, dissolve in 30 mL of boiling water and cool slightly. Add 3 mL of dilute hydrochloric acid TS, stir well and allow to cool to ambient temperature. Transfer the solution to a 50 mL volumetric flask, add water to volume, mix well, and centrifuge. Accurately measure 2 mL of the supernatant in a 25 mL volumetric flask, dilute to volume with the mobile phase and shake well.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.033 % potassium dihydrogen phosphate (30:70)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	2.681	5.521	27.92	277.5	7150	1.08

# Compound Yuxingcao Tablets (*Fufang Yuxingcao Pian*)

## 复方鱼腥草片

### Sample source

Commercially available Compound Yuxingcao Tablets

### Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

### Preparation of test solution

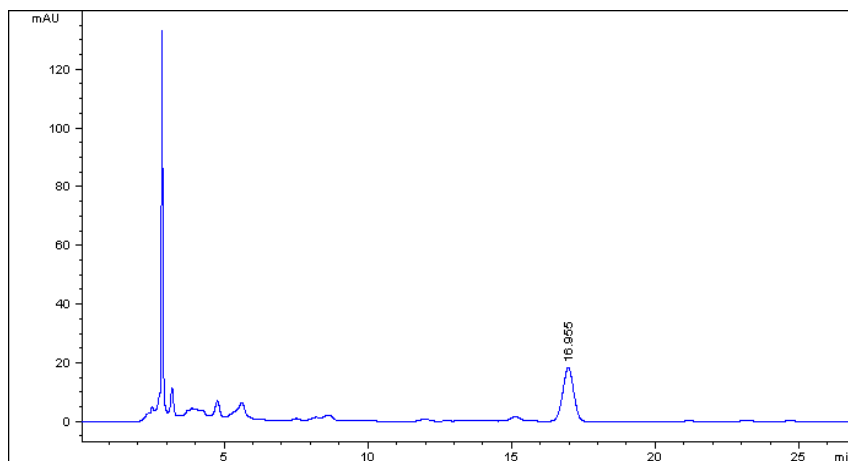
Accurately weigh 20 tablets, remove the coating and grind to a fine power. Put 0.25 g in a 50 mL volumetric flask, add 30 mL of 70 % ethanol. Treat ultrasonically for 30 minutes, allow to reach room temperature. Dilute with 70 % ethanol to volume, mix well, centrifuge and use the supernatant as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5  $\mu$ m (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-phosphoric acid (45:55:0.2)
- Detector wavelength: 315 nm
- Flow rate: 1.0 mL/min

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	5.782	16.955	18.27	484.2	9582	0.98

# Fuke Tiaojing Tablets (*Fuke Tiaojing Pian*) – 妇科调经片

## Sample source

Commercially available Fuke Tiaojing Tablets

## Chemical reference substances

ferulic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110773-9910)

## Preparation of test solution

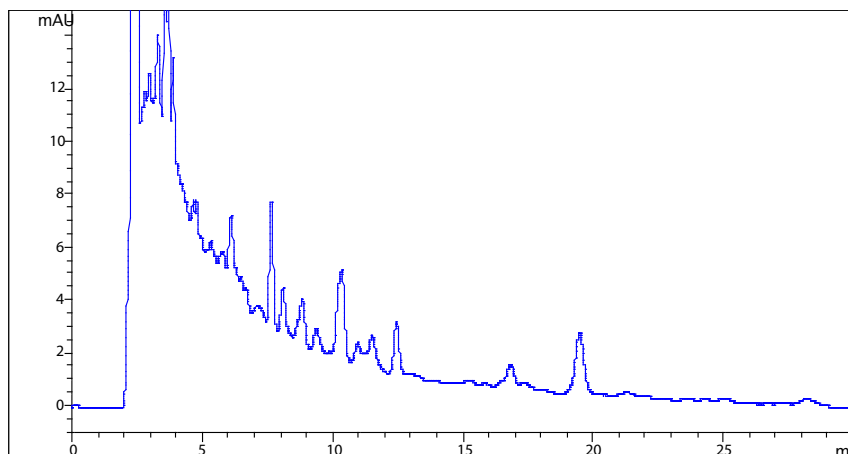
To 10 tablets with coating removed, weighed accurately, pulverized to fine powder, weighed accurately 1 g of the powder to a stopper conical flask. Add accurately 15 ml of methanol, stopped tightly, weighed accurately, ultrasonicate for 60 minutes, allow to cool, weighed accurately again, replenished the lost weight with methanol, mix well and filter. Discard the initial

## Chromatographic conditions

- Column: ZORBAX Eclipse Plus C18, 4.6×250mm, 5µm (959990-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1% phosphoric acid (30:70)
- Detector wavelength: 320nm
- Flow rate: 1.0 ml/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>f</sub>
Ferulic acid	19.483	2.34	56.5	16531	0.93

# Fuke Shiwei Tablets (*Fuke Shiwei Pian*) – 妇科十味片

## Sample source

Commercially available Fuke Shiwei Tablets

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

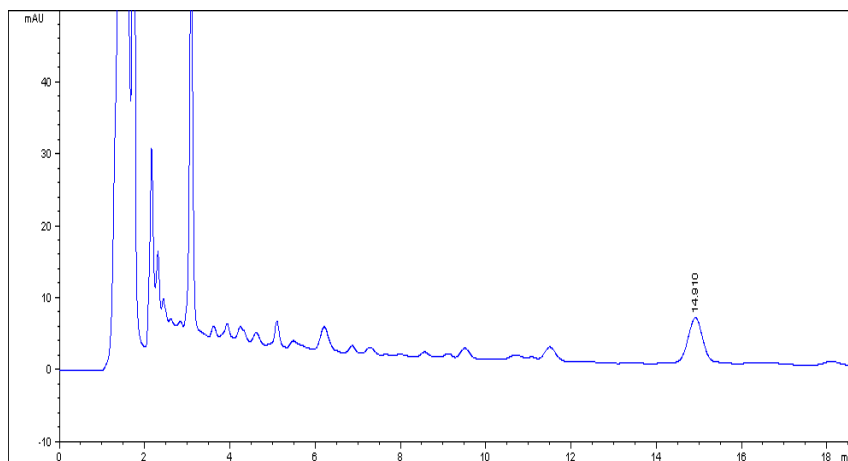
Grind 20 tablets, weighed accurately, into fine powder, weigh accurately 1 g in a stopper conical flask, add 25 ml of diluted ethanol, weigh and ultrasonicate for 30 minutes, allow to cool, weigh again, replenish the loss of weight with the diluted ethanol, and shake well. Filter

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.4 % phosphoric acid (12:88)
- Detector wavelength: 230 nm
- Flow rate: 1.0 ml/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	8.723	14.910	11.78	288.7	8224	1.01

# Liquorice Root (*Radix et Rhizoma Glycyrrhizae*) – 甘草<sup>1</sup>

## Sample source

Commercially available Liquorice Root

## Chemical reference substances

Glycyramarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111610-200401)

## Preparation of test solution

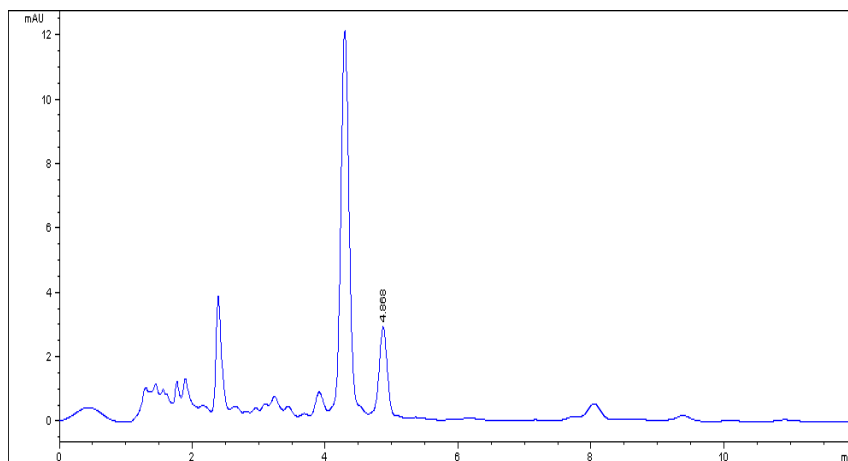
Accurately weigh 0.2 g of the powder in a stoppered conical flask, accurately add 10 mL of 70% ethanol and weigh. Treat ultrasonically for 30 minutes, take out and weigh again, replenish the lost weight with 70 % ethanol and filter. Accurately measure 5 mL of the filtrate in a 100 mL volumetric flask, dilute to volume with 20 % acetonitrile and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.5 % glacial acetic acid (1:4)
- Detector wavelength: 276 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>f</sub>
Glycyramarin	2.245	4.868	2.73	22.4	8246	0.95

# Liquorice Root (*Radix et Rhizoma Glycyrrhizae*) – 甘草<sup>2</sup>

## Sample source

Commercially available Liquorice Root

## Chemical reference substances

Ammonium glycyrrhizinate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0731-9704)

## Preparation of test solution

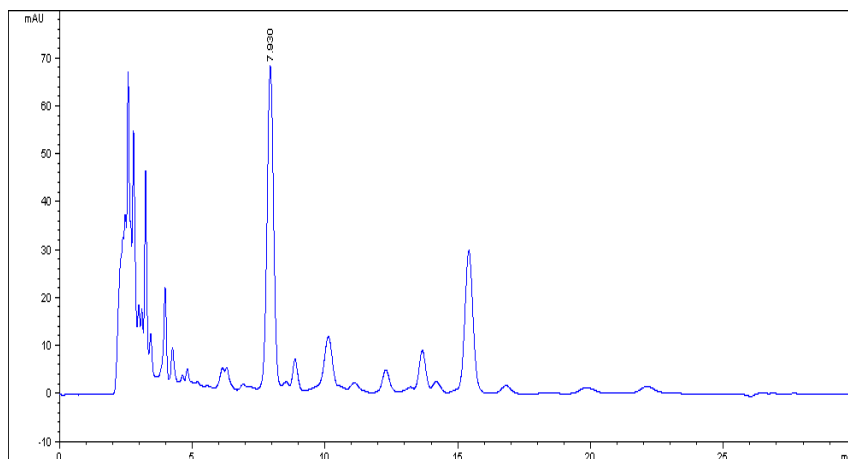
Accurately weigh 0.3 g of the powder in a 50 mL volumetric flask, add 45 mL of the mobile phase and treat ultrasonically for 30 minutes, take out and allow to cool, dilute with the mobile phase to volume and mix well, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.2mol/L ammonium acetate-glacial acetic acid (67:33:1)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Glycyrrhizinic acid	2.172	7.930	67.42	1149.4	5072	1.01

# Liquorice Extract (*Extractum Glycyrrhizae*) – 甘草浸膏

## Sample source

Commercially available prepared slices of Radix Glycyrrhizae

## Chemical reference substances

Ammonium glycyrrhizinate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0731-9704)

## Preparation of test solution

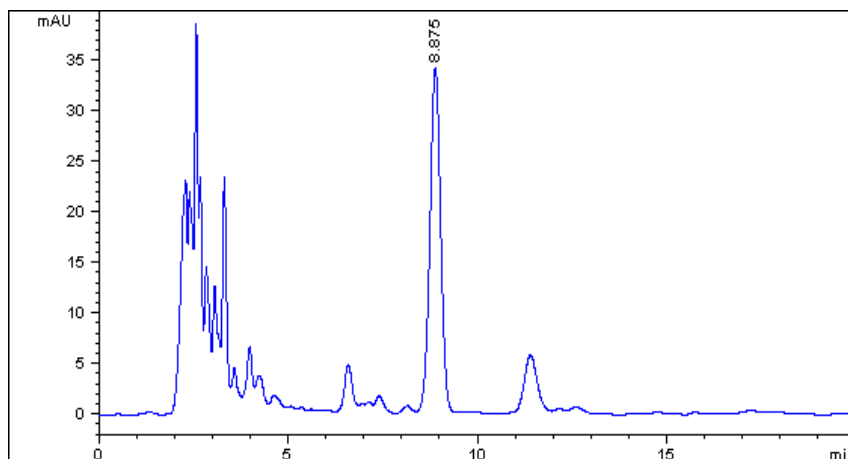
Add 4500 ml of water to 0.45 Kg prepared slices, decoct 3 times, 2 hours for each time. Combine the decoctions, stand overnight to deposit any precipitate and concentrate the supernatant to a thick extract. Accurately weigh 0.25 g in a 50 mL volumetric flask, add 45 mL of the mobile phase, treat ultrasonically for 30 minutes, allow to cool, add the mobile phase to volume, shake well and filter. Accurately measure 10 mL of the filtrate in a 25 mL volumetric flask, add the mobile phase to volume and shake well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.2mol/L ammonium acetate-glacial acetic acid (67:33:1)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Glycyrrhizinic acid	2.550	8.875	34.05	664.8	4898	0.98

# Liquorice Liquid Extract (*Extractum Glycyrrhizae Liquidum*)

甘草流浸膏

## Sample source

Commercially available prepared slices of *Radix Glycyrrhizae*

## Chemical reference substances

Ammonium glycyrrhizinate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0731-9704)

## Preparation of test solution

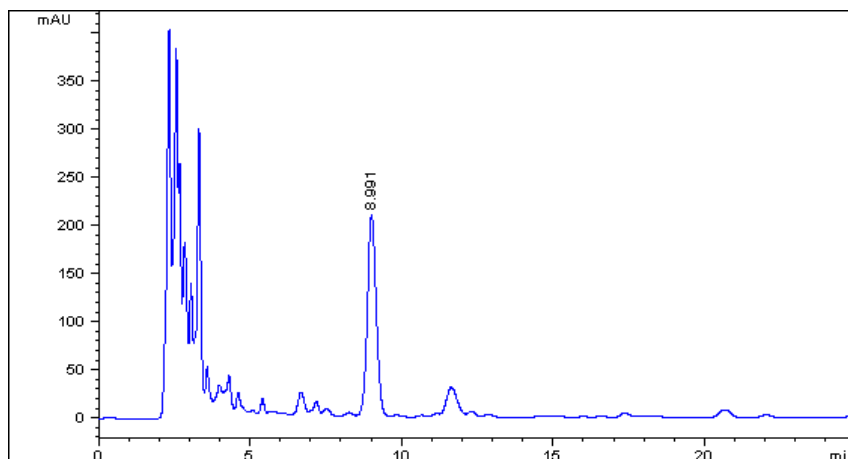
To 0.45 Kg prepared slices of *Radix Glycyrrhizae* add 4500 ml of water, decoct 3 times, 2 hours for each time. Combine the decoctions, stand over night to deposit any precipitate and concentrate the supernatant to a thick extract. Measure accurately 1 ml in a 25 ml volumetric flask, add 10 ml of the mobile phase, ultrasonicate for 30 minutes, cool, add the mobile phase to volume, shake well and filter. Use the successive filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.2mol/L ammonium acetate-glacial acetic acid (67:33:1)
- Detector wavelength: 250 nm
- Flow rate: 1.0 ml/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Glycyrrhizinic acid	2.596	8.991	210.78	4365.3	4570	1.05



# Ganmao Qingre Granules (*Ganmao Qingre Keli*) – 感冒清热颗粒

## Sample source

Commercially available Ganmao Qingre Granules

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110752-200209)

## Preparation of test solution

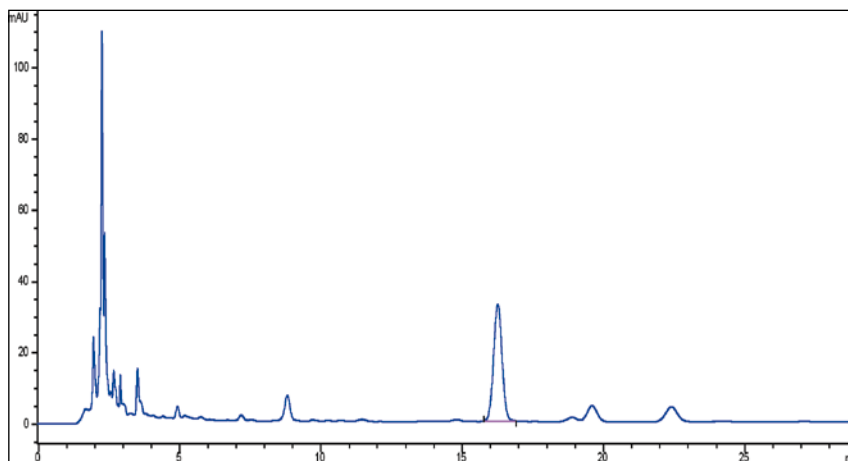
Grind a quantity of the granules to a fine powder, accurately weigh 0.8 g of the powder in a stoppered conical flask, accurately add 50 mL of 30 % ethanol, stopper tightly and weigh. Treat ultrasonically for 20 minutes, allow to reach room temperature, weigh again, replenish the lost weight with 30 % ethanol, shake thoroughly and filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test sample.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (11:89)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	5.504	16.26	32.79	692.2	14012	1.03

# Ganmao Tuire Granules (*Ganmao Tuire Keli*) – 感冒退热颗粒

## Sample source

Commercially available Ganmao Tuire Granules

## Chemical reference substances

Forsythin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110821-200305)

## Preparation of test solution

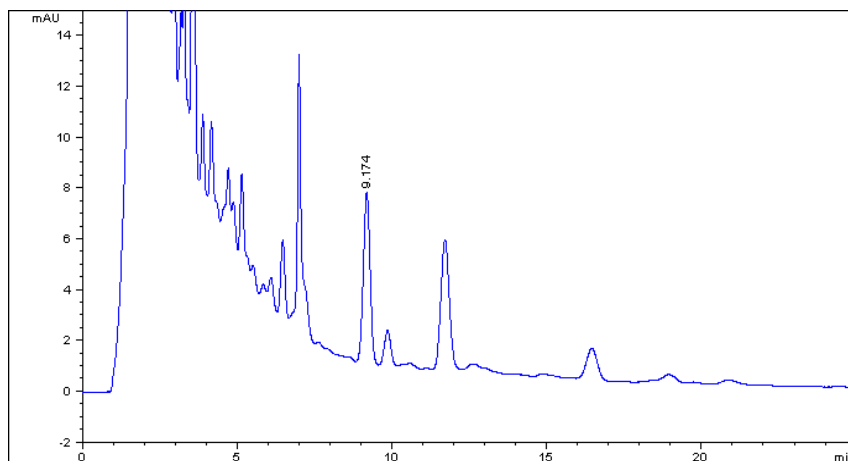
Accurately weigh 1.25 g of the granules without sucrose and grind to a fine power. Heat under reflux with two 25-mL quantities of methanol for 30 minutes, filter. Wash the filter funnel and the residue with 15 mL of methanol in portions, combine the washings and the filtrates, and evaporate to dryness. Dissolve the residue in 10 mL of 50 % ethanol, apply to a column (1 cm in diameter) packed with neutral alumina (100-200 mesh, 3 g), elute with 70 mL of 50 % ethanol, and collect the eluents. Evaporate to dryness and dissolve the residue in 50 % methanol, transfer to a 25 mL volumetric flask and dilute with 50 % ethanol to volume, mix well, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (21:79)
- Detector wavelength: 277 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Forsythin	5.116	9.174	6.73	102.1	8592	0.96

# Gegen Qinlian Pills (*Gegen Qinlian Wan*) – 葛根芩连丸

## Sample source

Commercially available Gegen Qinlian Pills

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110752-200209)

## Preparation of test solution

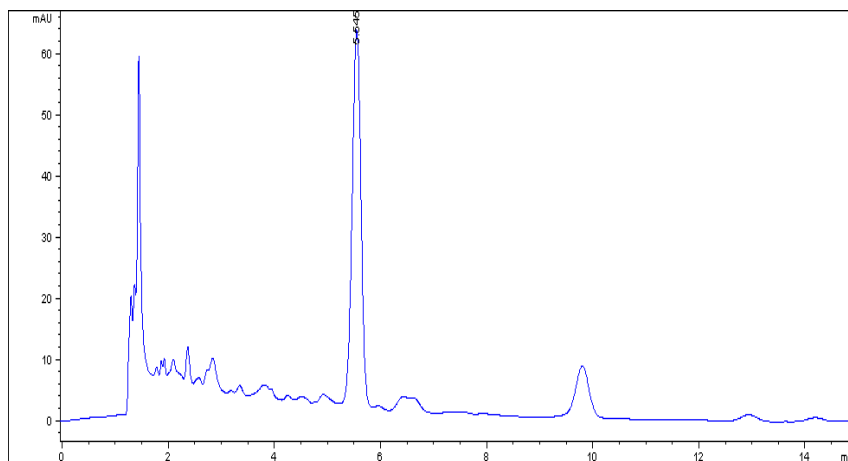
Grind a quantity of the pills to a fine powder and mix well, accurately weigh 0.3 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol, tightly stopper and weigh. Heat under reflux for 1 hour, allow to cool and weigh again, replenish the lost weight with methanol, shake thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 30 °C
- Mobile phase: acetonitrile-methanol-water (10:8:82)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>f</sub>
Puerarin	2.696	5.545	61.39	709.6	5257	0.95

# Gejie Dingchuan Pills (*Gejie Dingchuan Wan*) – 蛤蚧定喘丸

## Sample source

Commercially available Gejie Dingchuan Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

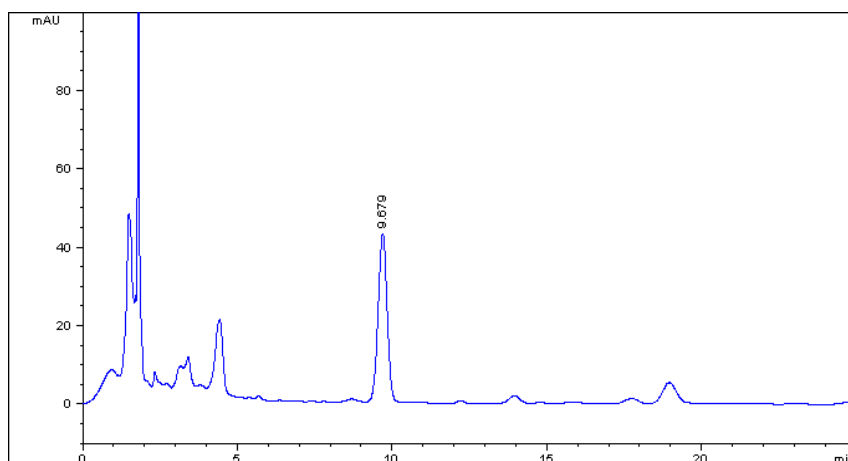
Grind a quantity of the pills to a fine power, accurately weigh 0.5 g of the powder in a 100 mL stoppered conical flask, accurately add 50 mL of 70 % ethanol, and weigh. Allow to soak warmly for 1 hour, heat under reflux for 30 minutes, allow to cool and weigh again, replenish the lost weight with 70 % ethanol, shake thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-3.6 % phosphoric acid (45:55)
- Detector wavelength: 276 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	7.066	9.679	42.92	864.4	5380	0.98

# Gentongping Granules (*Gentongping Keli*) – 根痛平颗粒

## Sample source

Commercially available Gentongping Granules

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

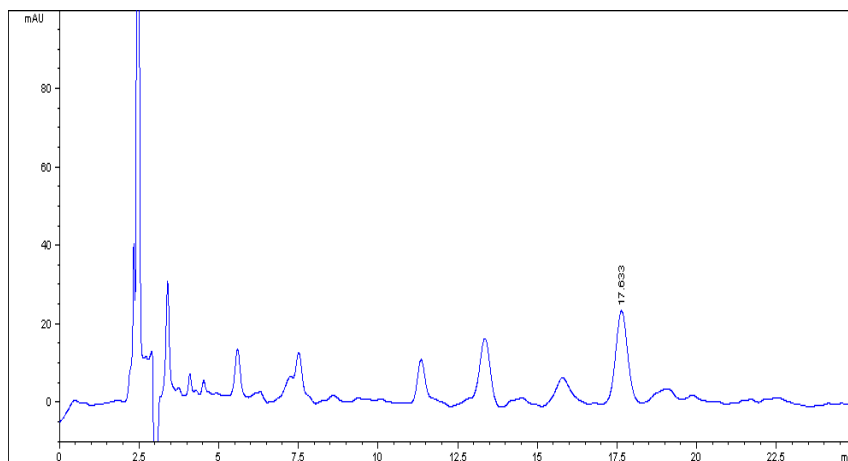
Grind a quantity of granules to a fine powder. Accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly and weigh, heat under reflux for 2 hours, allow to cool, weigh again, replenish the lost weight with methanol and mix well. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-1.5 % acetic acid (containing 0.1 % isopropanol) (23:77)
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	6.053	17.633	23.37	598.4	11145	1.03

# Chinese Mahonia Stem (*Caulis Mahoniae*) – 功劳木

## Sample source

Commercially available Chinese Mahonia Stem

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

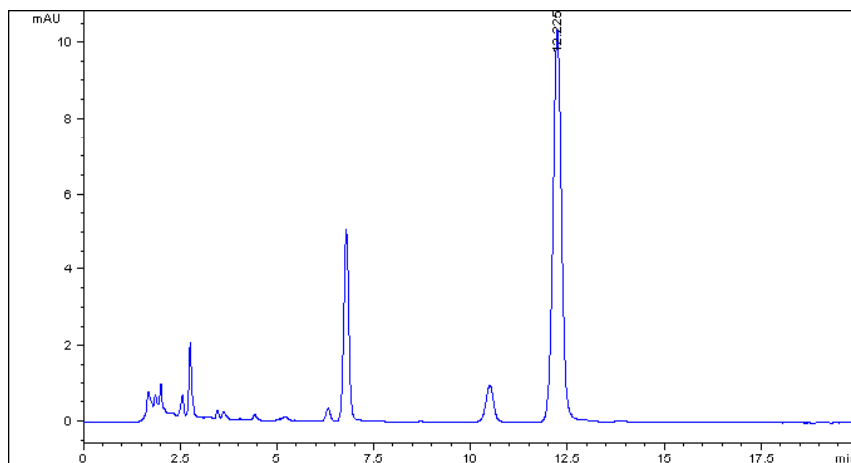
Accurately weigh 0.25 g of the coarse powder, accurately add 50 mL of a mixture of hydrochloric acid and methanol (1:100), weigh, allow to soak at room temperature for 30 minutes, treat ultrasonically for 45 minutes, allow to cool, weigh again, replenish the lost weight with a mixture of hydrochloric acid and methanol (1:100), mix well and filter. Accurately measure 5 mL of the filtrate in a flask and evaporate to dryness, dissolve the residue in a mixture of acetonitrile and water (3:7), transfer to a 5 mL volumetric flask, dilute to volume, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Eclipse Plus C18, 4.6×250 mm, 5 µm, P/N 959990-902
- Column temperature: 50 °C
- Mobile phase: acetonitrile-0.05mol/L potassium dihydrogen phosphate (pH 3.15) (25:75)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	5.148	15.37	91.8	1609.2	17258	1.28

# Gongxuening Capsules (*Gongxuening Jiaonang*) – 宫血宁胶囊

## Sample source

Commercially available Gongxuening Capsules

## Chemical reference substances

Chonglou saponin VI (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111592-200301)

## Preparation of test solution

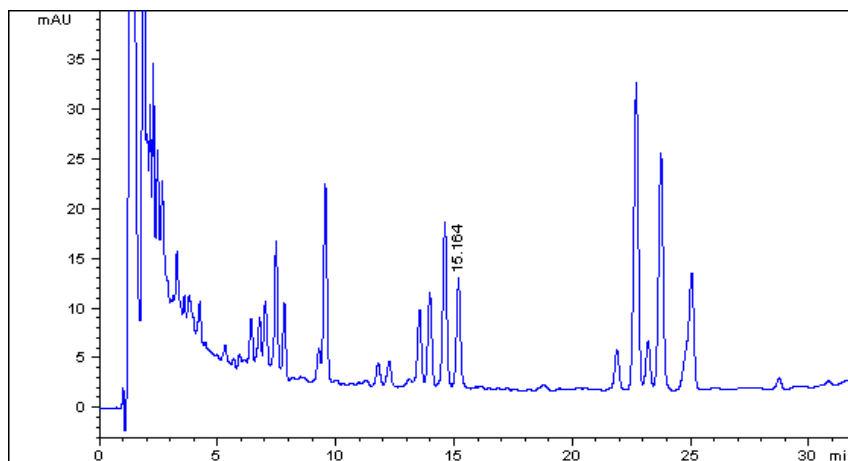
Grind the contents of 20 capsules to a fine powder, accurately weigh 1 g in a stoppered conical flask, accurately add 25 mL of methanol, and weigh. Treat ultrasonically for 40 minutes, allow to cool, weigh again, replenish the lost weight with methanol, and mix thoroughly.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 μm (993967-906)
- Column temperature: 25 °C
- Mobile phase: A: acetonitrile, B: water; 0-40 min, 30-60 % A.
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chonglou saponin VI	9.109	15.164	11.00	128.6	40968	0.99

# Guben Kechuan Tablets (*Guben Kechuan Pian*) – 固本咳喘片

## Sample source

Commercially available Guben Kechuan Tablets

## Chemical reference substances

1. Psoralen, 2. Isopsoralen (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110739-200309, 2. 110738-200309)

## Preparation of test solution

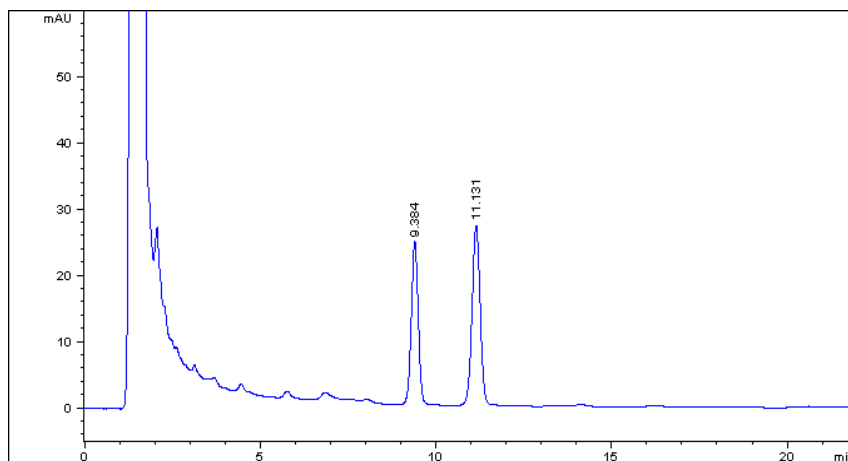
Accurately weigh 10 tablets, grind to a fine powder, accurately weigh 0.4 g of the powder in a stoppered conical flask, accurately add 20 mL of methanol, stopper tightly, and weigh. Treat ultrasonically for 40 minutes, cool, weigh again, replenish the lost weight with methanol, shake well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1mol/L disodium hydrogen phosphate solution (adjust pH value to 7.0 with 30 % phosphoric acid) (45:55)
- Detector wavelength: 246 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Psoralen		9.384	24.57	338.7	11180	1.00
Isopsoralen		11.131	27.10	438.2	11282	0.99



# Amur Cook Tree (*Cortex Phellodendri Amurensis*) – 关黄柏

## Sample source

Commercially available Amur Cork Tree

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

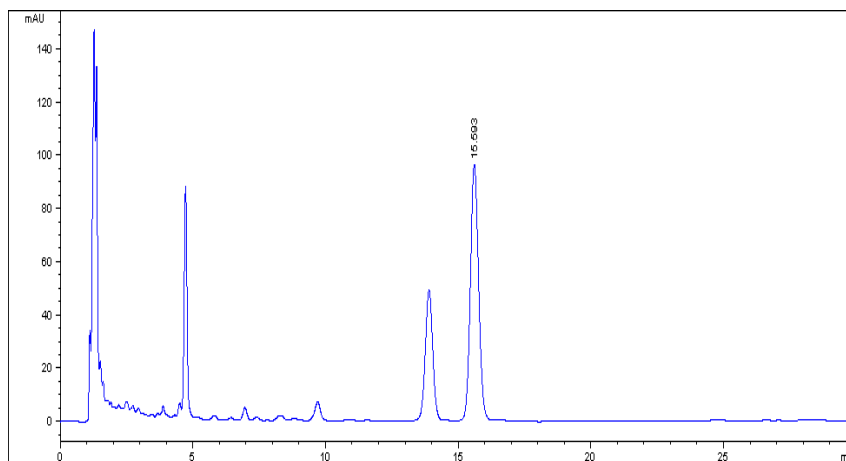
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of the mobile phase, weigh, treat ultrasonically for 40 minutes, allow to cool, weigh again, replenish the lost weight with the mobile phase, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 μm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (0.1 % phosphoric acid and 1 % sodium dodecylsulfonate) (50:50)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine hydrochloride	9.395	15.593	96.09	2055.8	12551	1.07

# Guishao Dihuang Pills (*Guishao Dihuang Wan*) – 归芍地黄丸

## Sample source

Commercially available Guishao Dihuang Pills

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110708-200205)

## Preparation of test solution

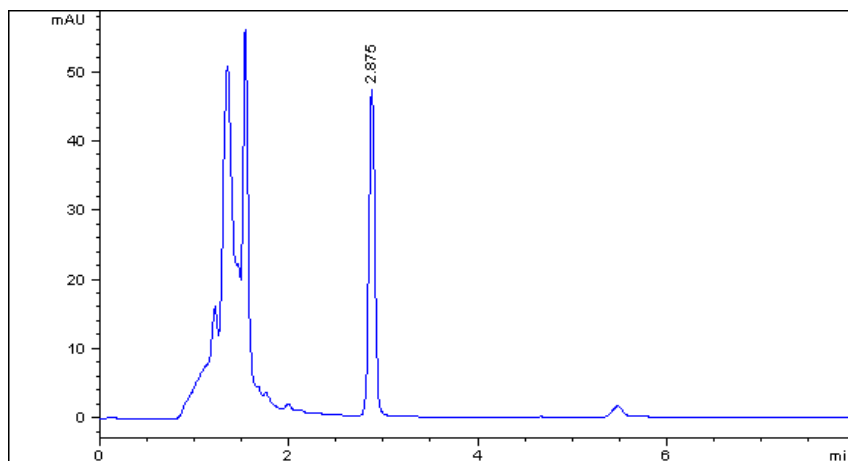
Cut a quantity of the pills into pieces and mix well, accurately weigh 0.4 g in a stoppered conical flask. Accurately add 50 mL of 70 % methanol, stopper tightly, weigh and treat ultrasonically for 45 minutes. Shake thoroughly, allow to reach room temperature, weigh again and replenish the lost weight with 70 % methanol, shake thoroughly, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (70:30)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol		2.875	47.33	208.4	10052	1.04

# Guishao Dihuang Pills (*Guishao Dihuang Wan*) – 归芍地黄丸

## Sample source

Commercially available Guishao Dihuang Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

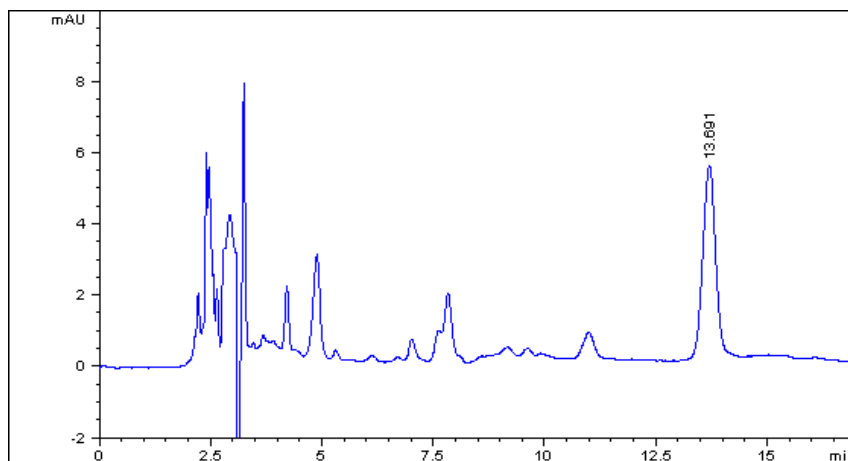
Cut a quantity of the pills into pieces and mixe well. Accurately weigh 0.4 g in a stoppered conical flask. Accurately add 50 mL of 70 % methanol, stopper tightly, weigh and treat ultrasonically for 45 minutes. Shake thoroughly, allow to reach room temperature, weigh again and replenish the lost weight with 70 % methanol, shake thoroughly, filter, accurately measure 25 mL of the filtrate, evaporate to dryness. Dissolve the residue in 25 mL of water by gently heating, allow to reach room temperature, extract with three 25 ml quantities of n-butanol saturated with water. Combine the n-butanol extracts, evaporate the solvent to dryness, dissolve the residue in an appropriate quantity of methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume and shake thoroughly as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (14:86)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin		13.691	5.41	107.4	11285	1.04

# Guifu Dihuang Pills (*Guifu Dihuang Wan*) – 桂附地黄丸

## Sample source

Commercially available Guifu Dihuang Pills

## Chemical reference substances

paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110708-200205)

## Preparation of test solution

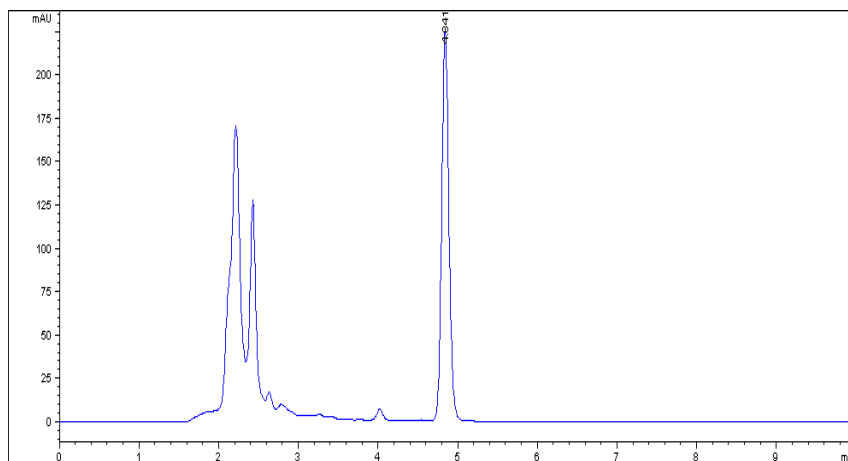
Accurately weigh 1 g of the pills, grind to a fine powder or cut into pieces and mix well, place in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 45 minutes, allow to reach room temperature and weigh again, replenish the lost weight with methanol, shake thoroughly and filter. accurately measure 25 mL of the filtrate, evaporate to dryness, dissolve the residue in methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume and shake thoroughly, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×250 mm, 5 μm (990967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (70:30)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	0.937	4.841	218.76	1406.2	14489	1.07

# Guifu Dihuang Pills (*Guifu Dihuang Wan*) – 桂附地黄丸

## Sample source

Commercially available Guifu Dihuang Pills

## Chemical reference substances

Loganin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111640-200401)

## Preparation of test solution

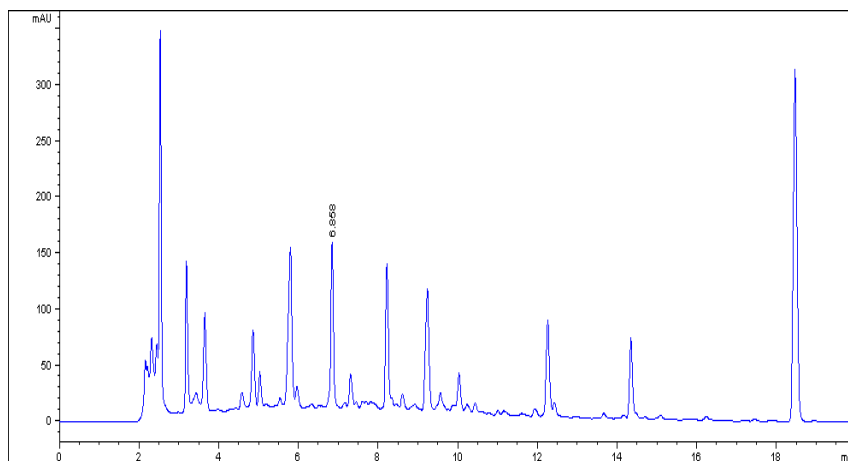
Accurately weigh 1 g of the pills, grind to a fine powder or cut into pieces and mix well, place in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 45 minutes, allow to reach room temperature and weigh again, replenish the lost weight with methanol, shake thoroughly and filter. accurately measure 25 mL of the filtrate, evaporate to dryness, dissolve the residue in methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume and shake thoroughly, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 30 °C
- Mobile phase: A: acetonitrile, B: 0.05 % phosphoric acid; 0-30 min, 11 % A, 30-35 min, 11-90 % A, 35-40 min, 90-11 % A.
- Detector wavelength: 236 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Loganin	1.743	6.858	147.17	682.7	57184	0.95

# Guilin Xiguashuan (*Guilin Xiguashuang*) – 桂林西瓜霜

## Sample source

Commercially available Guilin Xiguashuang

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

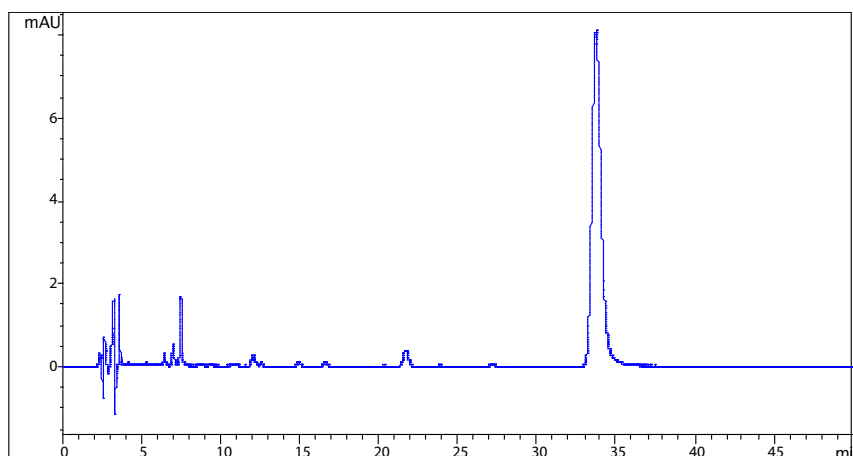
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of a mixture of hydrochloric acid-methanol (1:100), stopper tightly and weigh. Treat ultrasonically for 40 minutes, allow to reach room temperature, weigh again, replenish the lost weight with the above mixture, shake thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Eclipse Plus C18, 4.6×250 mm, 5 μm (959990-902)
- Column temperature: 20 °C
- Mobile phase: acetonitrile-0.05mol/L sodium dihydrogen phosphate solution (adjust pH value to 2.7 with phosphoric acid) (22:78)
- Detector wavelength: 350nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	12.496	33.741	8.1	322.6	16491	1.2

# Lotus Leaf (*Folium Nelumbinis*) – 荷叶

## Sample source

Commercially available Lotus Leaf

## Chemical reference substances

Nuciferine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111566-200201)

## Preparation of test solution

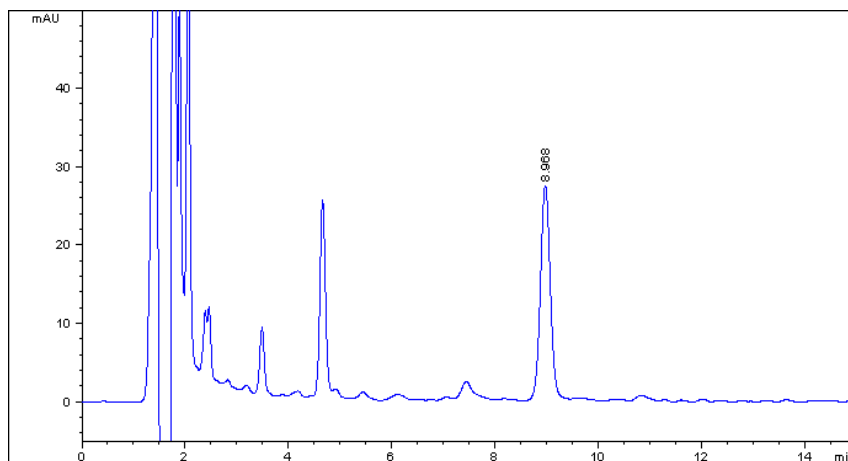
Accurately weigh 0.5 g of the coarse powder in a stoppered conical flask, accurately add 50 mL of methanol, weigh, heat under reflux on a water bath for 2.5 hours, allow to cool, weigh again, replenish the lost weight with methanol, mix well, and filter. Accurately measure 5 mL of the filtrate in a 10 mL volumetric flask, dilute with water to volume, and mix well. Filter with a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB-C18, 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (993967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water-triethylamine-glacial acetic acid (27:70.6:1.6:0.78)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Nuciferine	4.979	8.968	27.19	355.9	11253	1.04

# Heye Pills (*Heye Wan*) – 荷叶丸

## Sample source

Commercially available Heye Pills

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

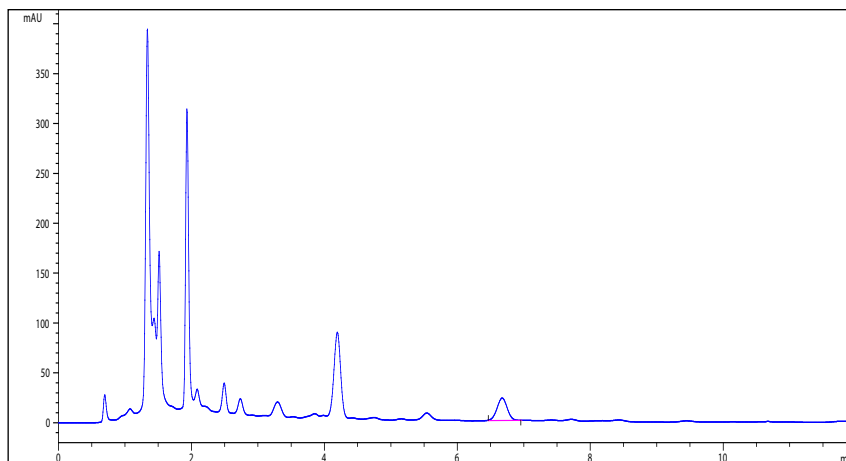
Cut a quantity of the pills into pieces and mix well, accurately weigh 1 g of the pieces in a stoppered conical flask, accurately add 10 mL of methanol, stopper and weigh, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well, filter through the millipore membrane (0.45 µm) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (15:85)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	4.562	6.675	22.50	240.2	9064	1.01



# Bigflower Rhodiola Root (*Radix et Rhizoma Rhodiolae*) – 红景天

## Sample source

Commercially available Bigflower Rhodiola Root

## Chemical reference substances

Salidroside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110818-200404)

## Preparation of test solution

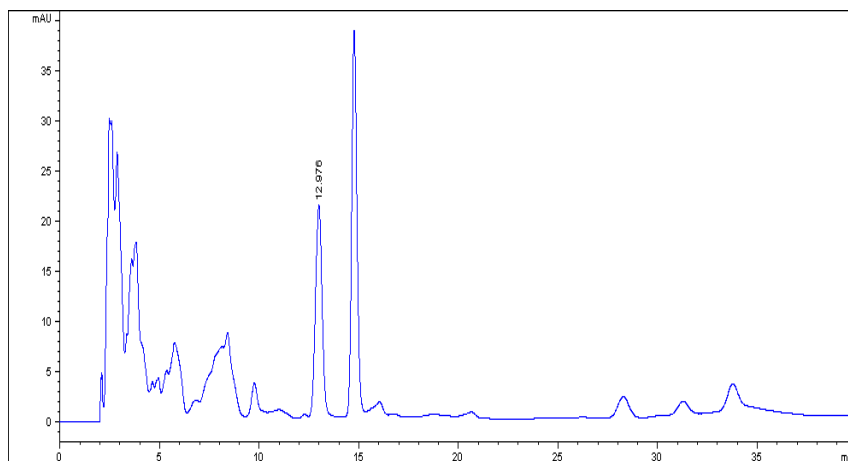
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 10 mL of methanol, mix well and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost solvent with methanol and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Extend C18 4.6×250 mm, 5 μm (770450-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (15:85)
- Detector wavelength: 275 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Salidroside	4.190	12.976	21.04	482.0	7332	1.01

# Red Ginseng (*Radix et Rhizoma Ginseng Rubra*) – 红参

## Sample source

Commercially available Red Ginseng

## Chemical reference substances

1. Ginsenoside Rb1, 2. Ginsenoside Rg1, 3. Ginsenoside Re (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 2. 110703-200322, 3. 0754-9912)

## Preparation of test solution

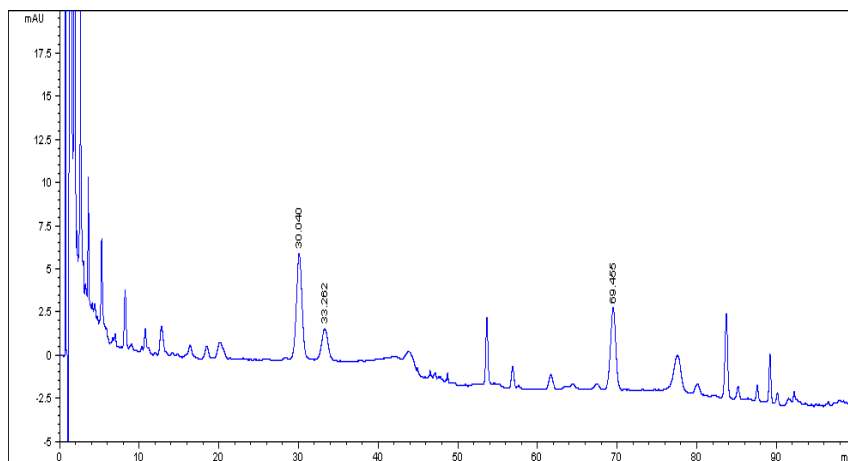
Accurately weigh 1 g of the powder in a Soxhlet extractor, add a quantity of chloroform, heat under reflux on a water bath for 3 hours, discard the chloroform solution, evaporate the solvent from the residue. Transfer the residue with the extractor to a 100 mL conical flask. Accurately add 50 mL n-butanol saturated with water, tightly stopper, allow to stand overnight, treat ultrasonically for 30 minutes and filter. Accurately evaporate 25 mL of the filtrate to dryness in an evaporating dish, dissolve the residue in methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: A: acetonitrile, B: water; 0-40 min, A: 19 %; 40-45 min, A: 19-28 %; 45-75 min, A: 28 %; 75-100 min, A: 28-40 %
- Detector wavelength: 203 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
ginsenoside Rg1	19.026	30.04	6.16	303.0	8834	1.00
ginsenoside Re	21.175	33.262	1.85	104.0	8213	0.98
ginsenoside Rb1	45.304	69.455	4.72	217.1	52506	0.96

# Official Magnolia Flower (*Flos Magnoliae Officinalis*) – 厚朴花

## Sample source

Commercially available Official Magnolia Flower

## Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1.0729-200006, 2.0730-9204)

## Preparation of test solution

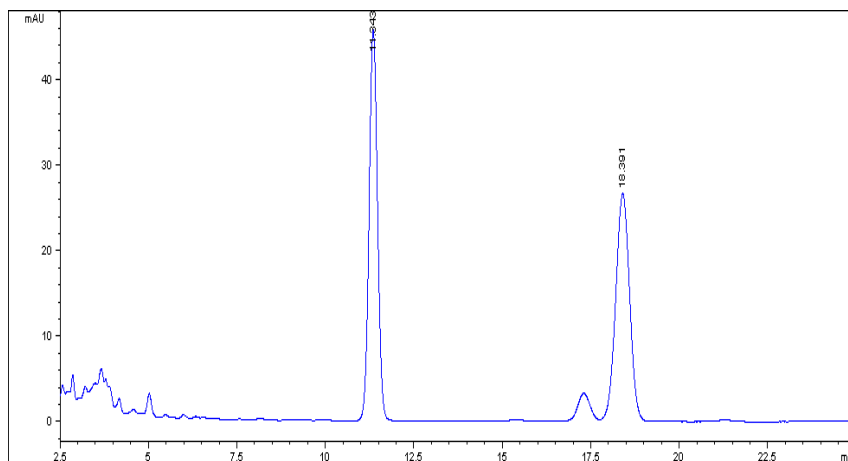
Accurately weigh 1 g of the coarse powder in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly and weigh, treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost weight with methanol and mix well, allow to stand for 30 minutes. Filter the supernatant liquid with a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (993967-906)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-methanol-water (20:45:35)
- Detector wavelength: 294 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
PHonokiol	6.562	11.343	45.67	756.4	10979	1.02
Magnolol	11.261	18.391	26.60	722.8	10510	0.99

# Common Fenugreek Seed (*Semen Trigonellae*) – 胡芦巴

## Sample source

Commercially available Common Fenugreek Seed

## Chemical reference substances

Trigonelline (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 883-200001)

## Preparation of test solution

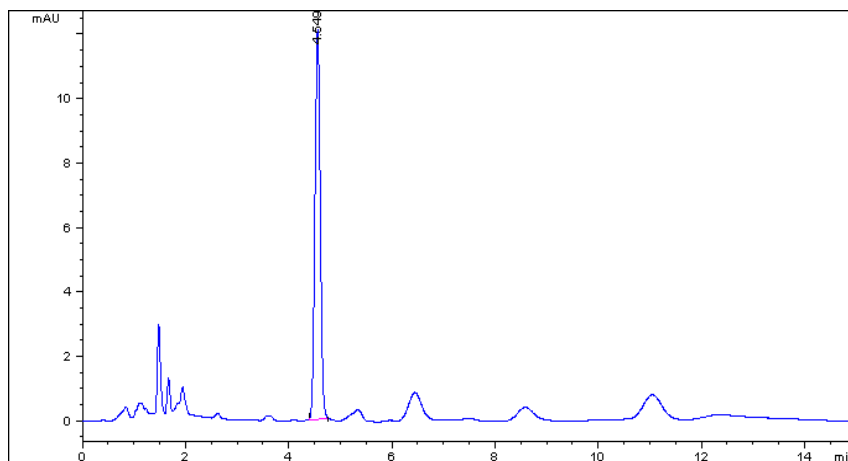
Accurately weigh 0.5 g of the powder in a conical flask, add 50 mL of 50 % methanol, and weigh. Allow to stand for 1 hour, treat ultrasonically for 45 minutes, allow to cool and weigh again, replenish the lost weight with 50 % methanol and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.3 % acetic acid-0.03 % sodium dodecyl sulfonate (20:0.1:80)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Trigonelline	2.033	4.549	12.10	85.5	9833	1.06

# Giant Knotweed (*Rhizoma et Radix Polygoni Cuspidati*) – 虎杖

## Sample source

Commercially available Giant Knotweed Rhizome

## Chemical reference substances

Emodin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110756-200210)

## Preparation of test solution

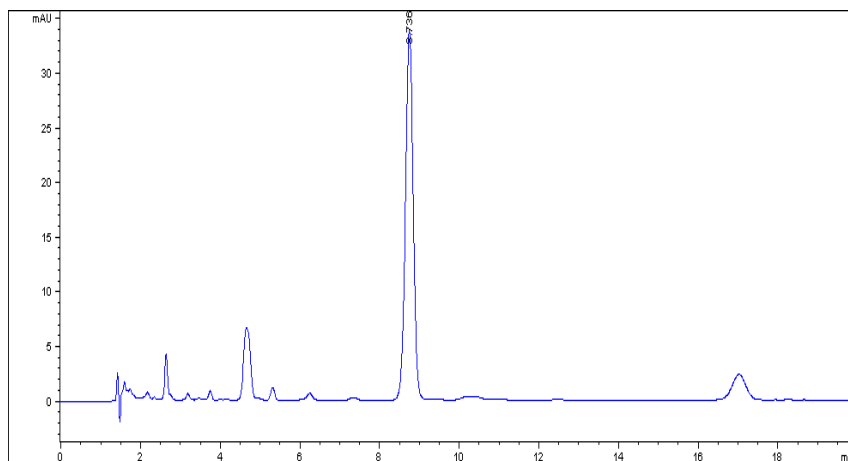
Accurately weigh 0.1 g of the powder in a stoppered conical flask, accurately add 25 mL of chloroform and 20 mL of sulfuric acid (2.5 mol/L), and weigh. Heat under reflux on a water bath at 80 °C for 2 hours, allow to cool and weigh again, replenish the lost solvent with chloroform and mix well. Separate the chloroform layer and evaporate accurately 10 mL to dryness. Dissolve the residue in methanol, transfer to a 10 ml volumetric flask, dilute to volume with methanol, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1 % phosphoric acid (75:25)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	4.824	8.736	32.61	469.8	9290	0.99

# Giant Knotweed (*Rhizoma et Radix Polygoni Cuspidati*) – 虎杖

## Sample source

Commercially available Giant Knotweed Rhizome

## Chemical reference substances

Polydatin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111575-200301)

## Preparation of test solution

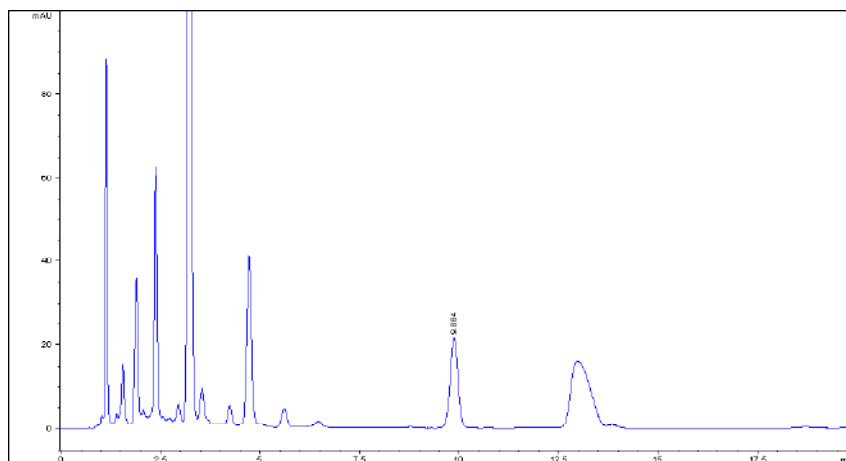
Accurately weigh 0.1 g of the powder, accurately add 25 mL of dilute ethanol and weigh, heat under reflux for 30 minutes, cool and weigh again, replenish the lost solvent with dilute ethanol and mix well. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (25:75)
- Detector wavelength: 306 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Polydatin		9.864	21.69	298.8	12095	1.01

# Hugan Tablets (*Hugan Pian*) – 护肝片

## Sample source

Commercially available Hugan Tablets

## Chemical reference substances

Schisandrin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110857-200203)

## Preparation of test solution

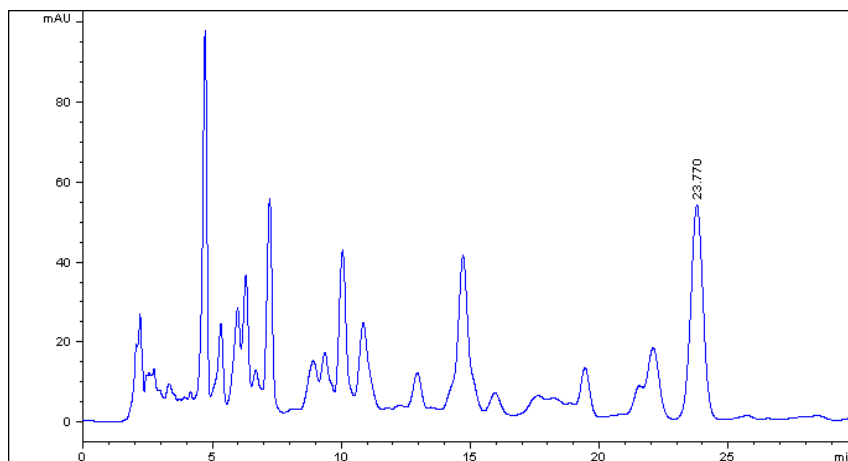
Take 10 tablets of the drug, remove the coating, accurately weigh and grind to a fine powder, accurately weigh 0.7 g of the powder, heat under reflux with 25 mL of ethyl acetate for 30 minutes, allow to cool, filter, wash the residue and the container with 30 mL of ethyl acetate in portions, filter, combine the washings and filtrate, evaporate to dryness, dissolve the residue with methanol and transfer to a 10 mL volumetric flask, dilute with methanol to volume, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (61:39)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Schisandrin	8.508	23.77	53.71	1763.4	12193	1.00

# Pagodatree Flower (carbonized) (*Flos Sophorae*) – 炒槐花

## Sample source

Commercially available Pagodatree Flower (carbonized)

## Chemical reference substances

Rutin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 100080-200306)

## Preparation of test solution

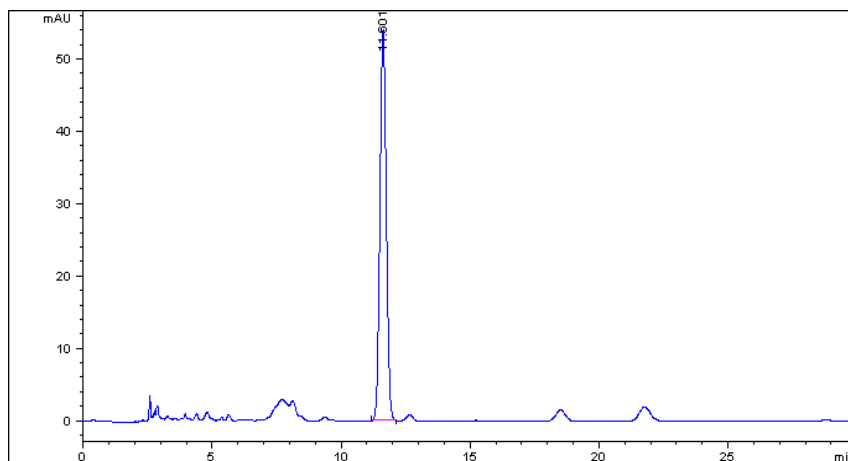
Accurately weigh 0.3 g of the coarse powder in a stoppered conical flask, accurately add 50 mL of methanol, weigh and treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost solvent with methanol, and mix well. Filter, accurately measure 2 mL of the filtrate in a 10 mL volumetric flask, add methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB-aq C18, 4.6×250 mm, 5 μm (880975-914)
- Column temperature: 40 °C
- Mobile phase: methanol-2 % glacial acetic acid (35:65)
- Detector wavelength: 257 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Rutin	3.64	11.60	54.01	924.2	10752	1.04



# Huaijiao Pills (*Huaijiao Wan*) – 槐角丸

## Sample source

Commercially available Huaijiao Pills

## Chemical reference substances

baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

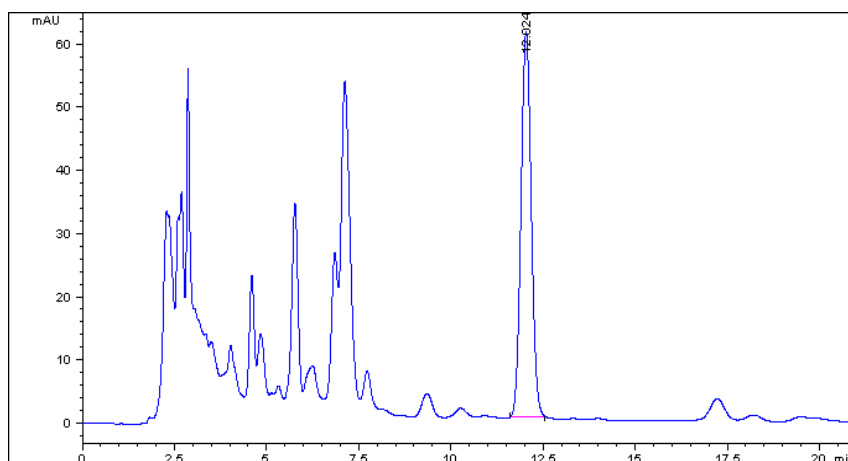
Accurately weigh 1.0 g of the pills in a pestle and grind with 80 mL of 50 % methanol, transfer to a 100 mL volumetric flask. Treat ultrasonically for 1 hour, allow to cool, dilute with 50 % methanol to volume, shake thoroughly and filter. Accurately measure 5 mL of the filtrate in a 10 mL volumetric flask, dilute with 50 % methanol to volume, shake thoroughly, filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 20  $^{\circ}\text{C}$
- Mobile phase: methanol-3.7 % glacial acetic acid (44:56)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	3.810	12.024	61.01	1179.7	9138	1.06

# Chinese Cork Tree (*Cortex Phellodendri Chinensis*) – 黄柏

## Sample source

Commercially available Chinese Cork Tree

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

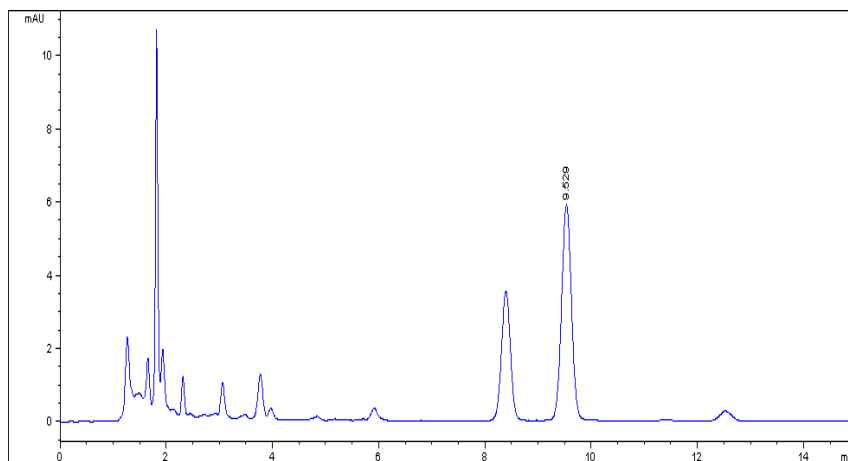
Accurately weigh 0.1 g of the powder in a 100 mL volumetric flask, add 80 mL of the mobile phase, treat ultrasonically for 40 minutes, allow to cool, dilute with the mobile phase to volume, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (contain 0.1 % sodium dodecylsulfonate)(50:50)
- Detector wavelength: 265 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	6.941	9.529	5.89	75.3	13019	1.02

# Huanglian Shangqing Pills (*Huanglian Shangqing Wan*)

## 黄连上清丸

### Sample source

Commercially available Huanglian Shangqing Pills

### Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

### Preparation of test solution

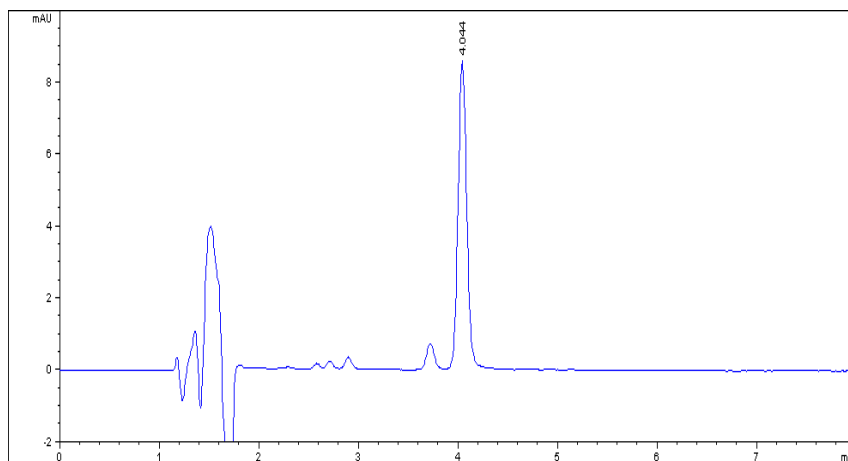
Accurately weigh 0.6 g of the pills, grind to a powder and put in a stoppered conical flask, accurately add 10 mL of a mixture of hydrochloric acid and methanol (1:100), stopper and weigh, heat in a water bath at 50 °C for 15 minutes, allow to reach room temperature, treat ultrasonically for 30 minutes, allow to reach room temperature, weigh again, replenish the lost weight with methanol, mix well, centrifugate and filter. Accurately measure 2 mL of the filtrate, evaporate to dryness at a lower temperature, dissolve the residue in a quantity of methanol and apply to a column (1 cm in diameter) packed with alkaline aluminum oxide (100-200 mesh, 8 g). Elute with 35 mL of methanol, collect the elutes and evaporate to dryness, dissolve the residue in a quantity of methanol and transfer to a 2 mL volumetric flask, dilute with methanol to volume, mix well, filter and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-potassium dihydrogen phosphate (35:65)
- Detector wavelength: 424 nm
- Flow rate: 1.0 mL/min

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	1.696	4.044	8.56	50.9	11184	1.09

# Milkvetch Root (*Radix Astragali*) – 黄芪

## Sample source

Commercially available Milkvetch Root

## Chemical reference substances

Astragaloside IV (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0781-9807)

## Preparation of test solution

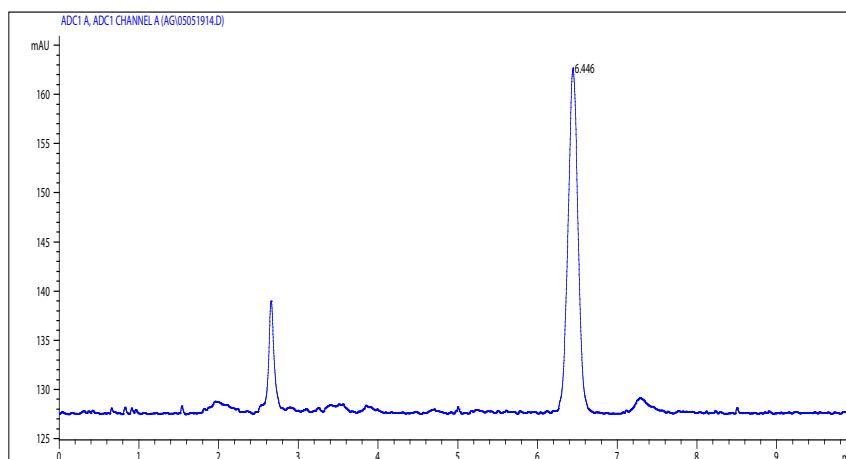
Accurately weigh 4 g of the powder in a Soxhlet extractor, add 40 mL of methanol, allow to soak overnight, add again an appropriate quantity of methanol, heat under reflux on a water bath for 4 hours and concentrate the extracts to dryness. Add 10 mL of water and slightly heat to dissolve the residue, extract by shaking with four 40-ml quantities of n-butanol saturated with water, combine the extracts and wash with two 40 ml quantities of ammonia TS. Discard the ammonia solutions and evaporate the n-butanol extracts to dryness, dissolve the residue in 5 mL of water and cool. Apply it to a column packed with D101 macroporous resin, elute with 50 mL of water, 30 mL of 40 % ethanol, and 80 mL of 70 % ethanol successively, discard the water and 40 % ethanol eluents, collect the 70 % ethanol eluents and evaporate to dryness. Dissolve the residue in methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX Extend C18 4.6×250 mm, 5 µm (770450-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (35:65)
- Evaporator tube temperature: 80° C, Nebulizing temperature: 50° C, Air flow rate: 1.5 SLM
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD PL-ELS 1000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Astragaloside IV	1.578	6.446	34.93	302.6	13113	1.00

# Baical Skullcap Extrtact (*Extractum Scutellariae Siccus*)

## 黄芩提取物

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### Sample source

Commercially available Baical Skullcap Extract

### Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

### Preparation of test solution

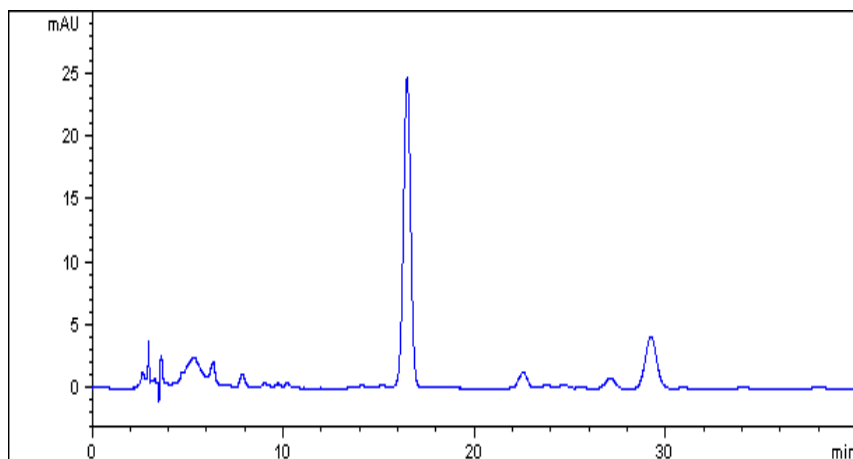
Accurately weigh 10 mg in a 25 mL volumetric flask, add methanol to volume and shake well. Accurately measure 5 mL in a 25 mL volumetric flask, add methanol to volume, shake well, filter, and use the filtrate as the test solution.

### Chromatographic conditions

- Column: Agilent TC-C18, 4.6×250 mm, 5 µm (518925-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.38 % phosphoric acid (47:53)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	n	USP T <sub>r</sub>
Baicalin	5.60	16.51	8986	0.97

# Huixiang Juhe Pills (*Huixiang Juhe Wan*) – 茴香橘核丸

## Sample source

Commercially available Huixiang Juhe Pills

## Chemical reference substances

1. Psoralen, 2. Isopsoralen (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110739-200309, 2. 110738-200309)

## Preparation of test solution

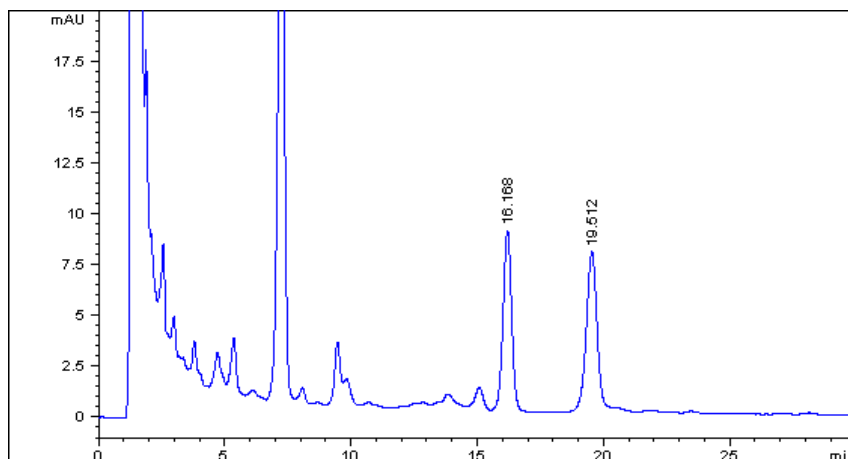
Grind a quantity of the pills to a fine powder, accurately weigh 2 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly and weigh, treat ultrasonically for 50 minutes, allow to cool, weigh again and replenish the lost weight with the same solvents, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.02mol/L dipotassium hydrogen phosphate (20:80)
- Detector wavelength: 247 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
sPsoralen	9.779	16.168	8.86	205.5	11823	0.98
Isopsoralen	12.008	19.512	7.79	225.1	11233	0.98

# Huoxue Zhitong Powder (*Huoxue Zhitong San*) – 活血止痛散

## Sample source

Commercially available Huoxue Zhitong Powder

## Chemical reference substances

Ferulic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110773-9910)

## Preparation of test solution

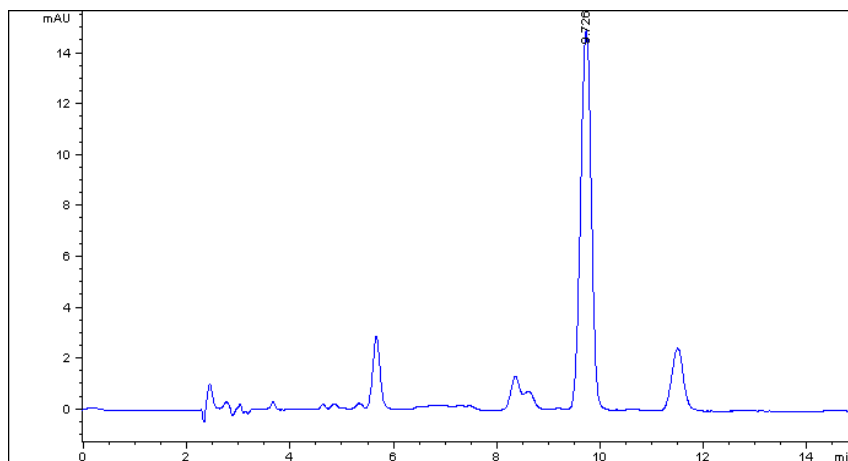
Accurately weigh about 2.3 g of the powder in a stoppered conical flask, add 20 mL of a 0.5 % solution of sodium carbonate, treat ultrasonically for 30 minutes, transfer the solution to a centrifuge tube, centrifugate at 3000 rpm for 10 minutes, and transfer the supernatant to a separating funnel. Wash the precipitate with three 10 ml quantities 0.5 % solution of sodium carbonate, combine the washings in the same separating funnel, extract with three 20 ml quantities of ether saturated with 2 % solution of sodium chloride, discard the ether layer and adjust the solution pH to 1-2 with hydrochloric acid, then extract the solution with two 25 ml and two 20 ml quantities of ether saturated with 2 % solution of sodium chloride. Combine the ether layer and remove the solvent from the extract to dryness, dissolve the residue in methanol and transfer to a 25 mL amber volumetric flask, dilute with methanol to volume, mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-methanol-1 % glacial acetic acid (14.2:14.2:71.6)
- Detector wavelength: 313 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ferulic acid	2.890	9.726	14.92	215.5	10403	0.96

# Huoxiang Zhengqi Oral Liquid (*Huoxiang Zhengqi Koufuye*)

## 藿香正气口服液

### Sample source

Commercially available Huoxiang Zhengqi Oral Liquid

### Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110729-200308, 2. 110730-9204)

### Preparation of test solution

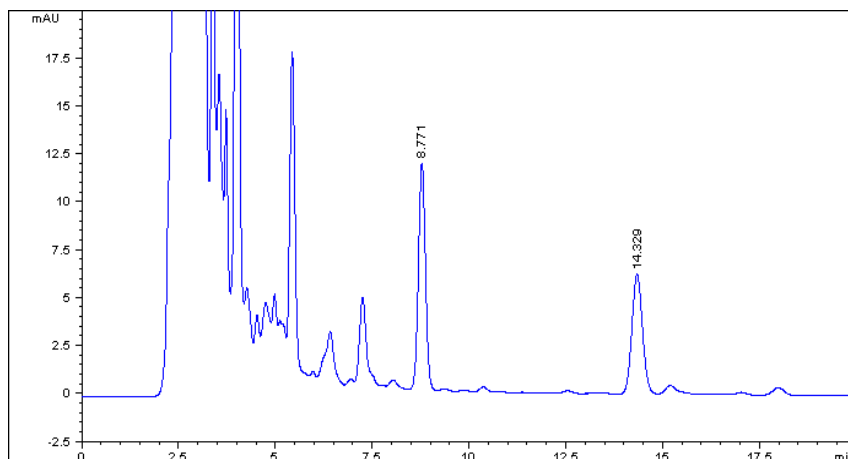
Accurately measure 5 mL of the liquid, add 2 drops of hydrochloric acid, extract with three 10 mL quantities of chloroform, combine the chloroform extracts and evaporate to dryness, dissolve the residue in a quantity of methanol, transfer the methanol solution to a 10 mL volumetric flask, dilute with methanol to volume, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (990967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-isopropanol-water (47:20:33)
- Detector wavelength: 300 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Honokiol	2.508	8.771	11.83	148.5	11597	1.03
Magnolol	4.731	14.329	6.25	118.6	13192	1.06



# Huoxiang Zhengqi Soft Capsules (*Huoxiang Zhengqi Ruanjiaonang*)

## 藿香正气软胶囊

### Sample source

Commercially available Huoxiang Zhengqi Soft Capsules

### Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110729-200308, 2. 110730-9204)

### Preparation of test solution

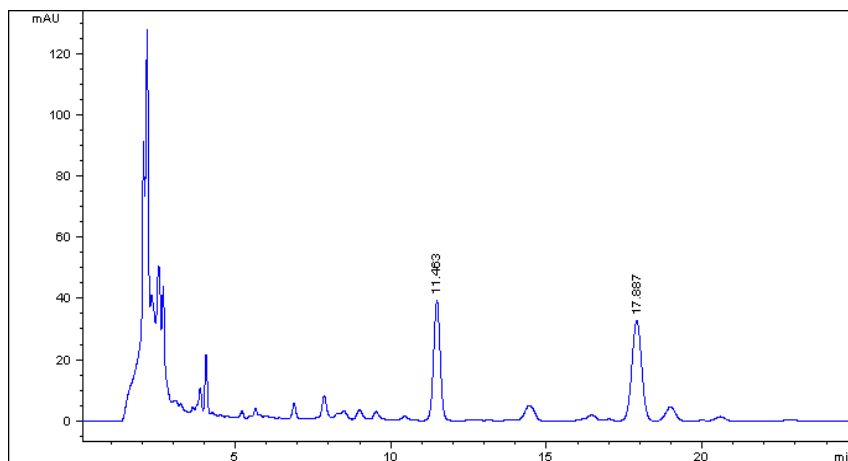
Cut open 15 capsules, collect the contents and mix well. Accurately weigh 0.25 g of the contents in a stoppered conical flask, accurately add 50 mL of 50 % ethanol, stopper tightly and weigh. Treat ultrasonically for 10 minutes, allow to reach room temperature and weigh again, replenish the lost weight with 50 % ethanol, shake thoroughly and filter, use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18, 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (71:29)
- Detector wavelength: 294nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Honokiol	3.589	11.463	39.37	577.1	14606	0.99
Magnolol	6.155	17.887	32.75	709.1	15579	1.00

# Huoxiang Zhengqi Tincture (*Huoxiang Zhengqi Shui*)

## 藿香正气水

### Sample source

Commercially available Huoxiang Zhengqi Tincture

### Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110729-200308, 2. 110730-9204)

### Preparation of test solution

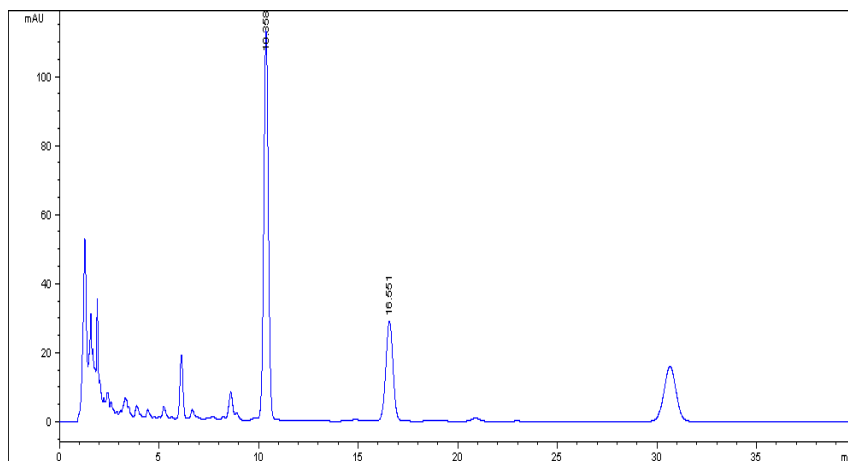
Accurately measure 5 mL of the solution, add 2 drops of hydrochloric acid, extract with three 10 ml quantities of chloroform. Combine the chloroform solutions, evaporate to dryness, dissolve the residue in methanol and transfer to a 10 mL volumetric flask, dilute with methanol to volume, mix well, filter and use filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-acetonitrile-water (45:20:35)
- Detector wavelength: 294nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Honokiol	5.905	10.358	113.24	1813.8	9894	1.03
Magnolol	10.034	16.551	28.82	721.3	10324	0.99

# Jiawei Xiaoyao Pills (*Jiawei Xiaoyao Wan*) – 加味逍遥丸

## Sample source

Commercially available Jiawei Xiaoyao Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

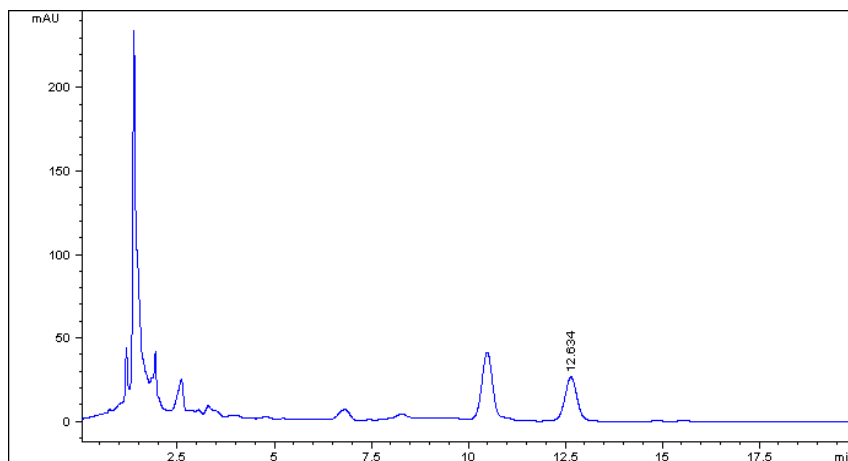
Grind the pills to a fine powder, accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 50 mL of dilute ethanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again and replenish the lost weight with dilute ethanol. Mix thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (23:77)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	9.528	12.634	26.00	550.9	8363	1.02

# Jianmin Yanhou Tablets (*Jianmin Yanhou Pian*) – 健民咽喉片

## Sample source

Commercially available Jianmin Yanhou Tablets

## Chemical reference substances

Gallic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110831-9501)

## Preparation of test solution

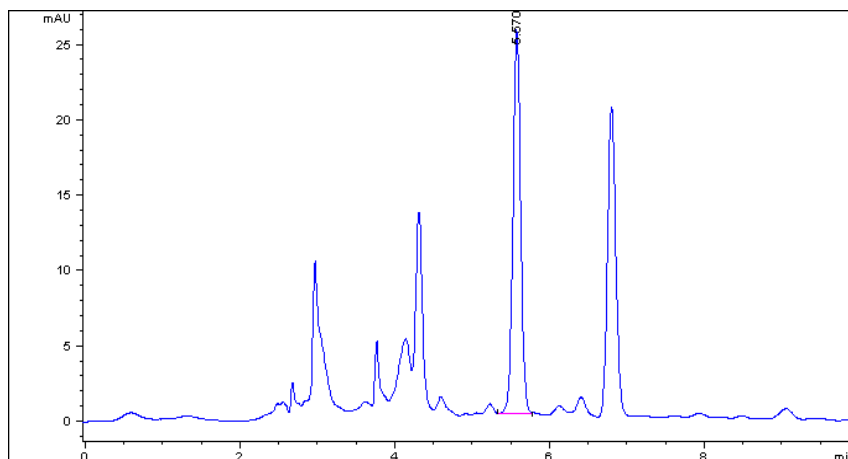
Accurately weigh 20 tablets, removed the coating, grind to a powder and mix thoroughly, accurately weigh 1.5 g of the powder in a stoppered conical flask, accurately add 50 mL of 50 % methanol, stopper tightly and weigh, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 50 % methanol and mix thoroughly. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB-aq C18, 4.6×250 mm, 5 µm (880975-914)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-(0.1% triethylamine + 0.1% phosphoric acid (7:93))
- Detector wavelength: 273 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Gallic acid	1.228	5.570	25.50	177.5	15491	1.03

# Jianwei Xiaoshi Tablets (*Jianwei Xiaoshi Pian*) – 健胃消食片

## Sample source

Commercially available Jianwei Xiaoshi Tablets

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0721-200211)

## Preparation of test solution

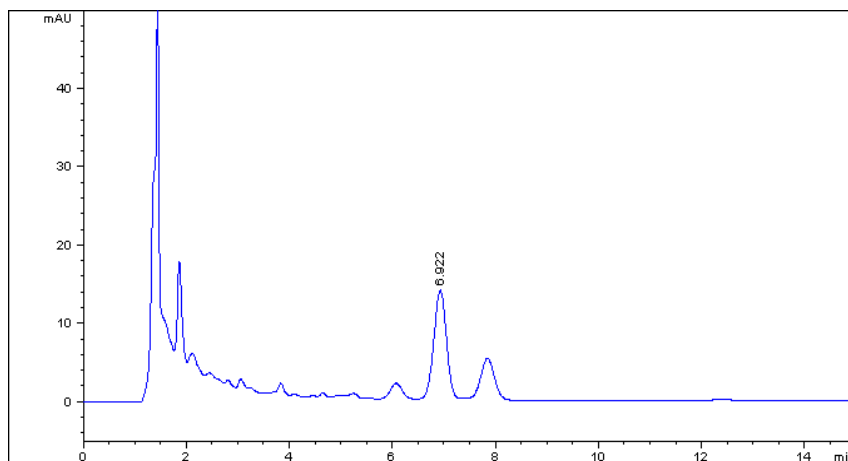
Grind 10 tablets to a fine powder. Accurately weigh 0.2 g of the powder, accurately add 20 mL of methanol, weigh, heat under reflux for 1 hour, allow to cool, weigh again, and replenish the lost weight with methanol, mix well and filter. Accurately measure 5 mL of the filtrate in a 10 mL volumetric flask and dilute with water to volume, mix well and filter, use the filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-0.5% glacial acetic acid (40:60)
- Detector wavelength: 283nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Hesperidin	3.615	6.922	13.86	234.5	3828	0.98

# Turmeric (*Rhizoma Curcumae Longae*) – 姜黄

## Sample source

Commercially available Turmeric

## Chemical reference substances

Curcumin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110823-9802)

## Preparation of test solution

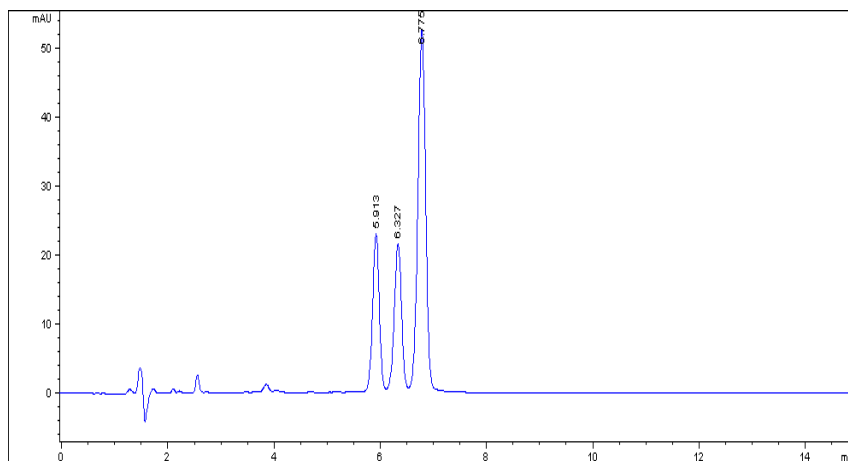
Accurately weigh 0.2 g of the fine powder in a stoppered conical flask. Accurately add 10 mL of methanol, weigh, heat under reflux for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and centrifuge. Accurately measure 1 mL of the supernatant in a 20 mL volumetric flask, dilute with methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-906)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-4% glacial acetic acid (45:55)
- Detector wavelength: 430 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Curcumin	3.517	6.775	52.29	525.7	10585	0.97

# Jinguo Tablets (*Jinguo Hanpian*) – 金果含片

## Sample source

Commercially available Jinguo Tablets

## Chemical reference substances

Hesperadin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110721-200211)

## Preparation of test solution

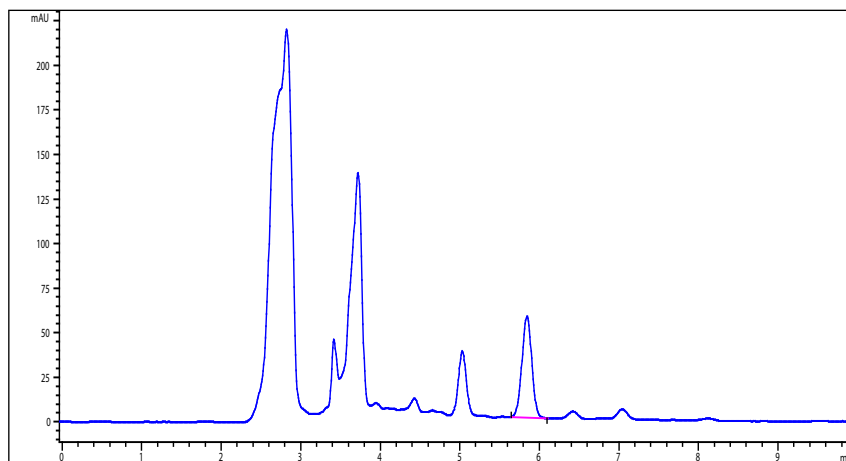
Accurately weigh 20 tablets, grind to a fine powder; accurately weigh 2 g of the powder, put in a Soxhlet extractor, add 80 mL of methanol, heat under reflux until the extract is colorless and allow to cool. Transfer the extract to a 100 mL volumetric flask, wash the vessel with a quantity of methanol several times, add the washings to the same volumetric flask, and dilute with methanol to volume. Mix thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-1.5% glacial acetic acid (26:74)
- Detector wavelength: 284nm
- Flow rate: 0.8 ml/min
- Injection volume: 5 µl

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	0.870	5.845	56.97	493.0	10917	0.97

# Common Clubmoss Herb (*Herba Lysimachiae*) – 金钱草

## Sample source

Commercially available Common Clubmoss Herb (Jiangsu province)

## Chemical reference substances

1. Quercetin, 2. Kaempferol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 0081-9905, 2. 0864-9901)

## Preparation of test solution

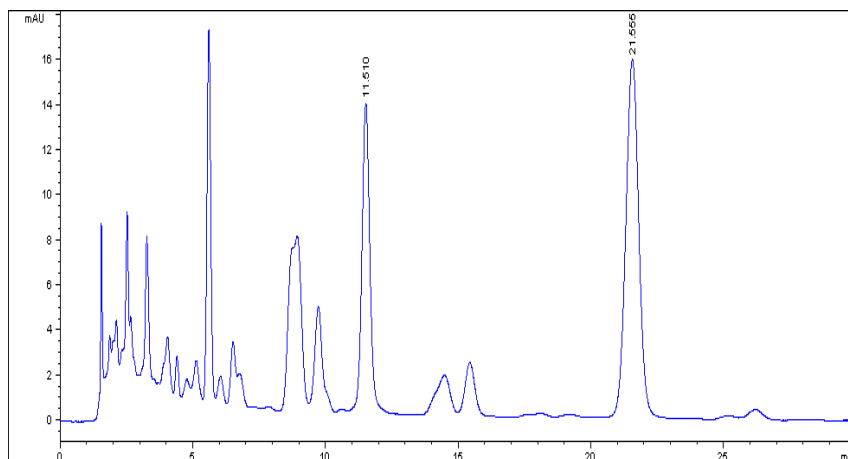
Accurately weigh 1.5 g of the powder in a stoppered conical flask. Accurately add 50 mL of 80 % methanol, weigh, and heat under reflux on a water bath for 1 hour, allow to cool, weigh again, replenish the lost weight with 80 % methanol, mix well and filter. Accurately measure 25 mL of the filtrate, accurately add 5 mL of hydrochloric acid, heat on a water bath at 90 °C for 1 hour, cool immediately. Transfer to a 50 mL volumetric flask, dilute with 80 % methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.4 % phosphoric acid (45:55)
- Detector wavelength: 360 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Quercetin	8.592	11.510	13.51	266.7	8106	1.05
Kaempferol	16.962	21.555	15.80	525.9	9725	1.01



# Jinsang Liyan Pills (*Jinsang Liyan Wan*) – 金嗓利咽丸

## Sample source

Commercially available Jinsang Liyan Pills

## Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110729-200308, 2.110730-9204)

## Preparation of test solution

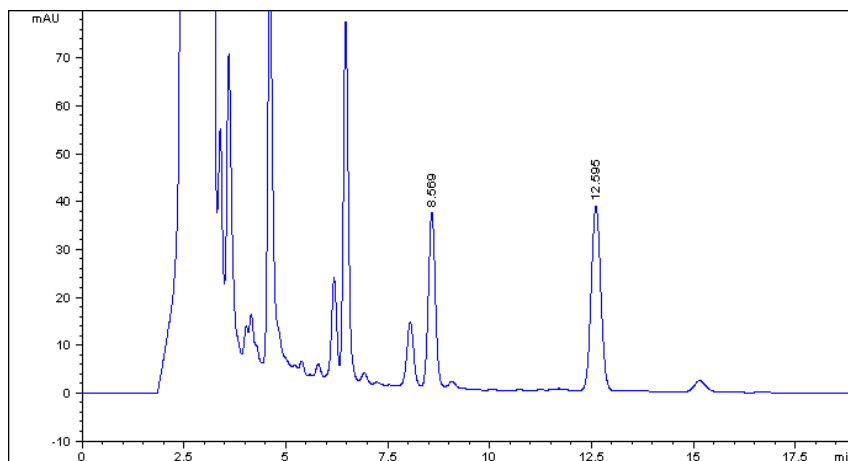
Grind 8 g of pills to a fine powder, accurately weigh 1.5 g in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly, and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (990967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-water (76.5:23.5)
- Detector wavelength: 291 nm
- Flow rate: 0.9 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Honokiol	2.085	8.569	36.45	425.2	12614	1.05
Magnolol	3.534	12.595	38.49	621.4	14068	1.05

# Jinsang Sanjie Pills (*Jinsang Sanjie Wan*) – 金嗓散结丸

## Sample source

Commercially available Jinsang Sanjie Pills

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110753-200212)

## Preparation of test solution

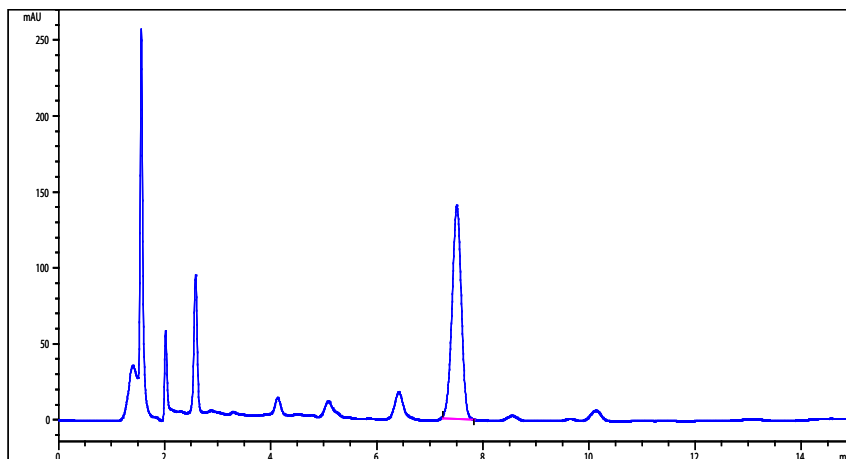
Grind a quantity of the pills to a fine powder, accurately weigh 0.4 g in a stoppered conical flask, accurately add 10 mL of 50 % methanol, stopper tightly, and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 50 % methanol, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.4% phosphoric acid (13:87)
- Detector wavelength: 330 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	5.257	7.508	140.74	1708.3	9023	0.95

# Japanese Honeysuckle Flower (*Flos Lonicerae Japonicae*)

金银花

## Sample source

Commercially available Japanese Honeysuckle Flower

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110753-200212)

## Preparation of test solution

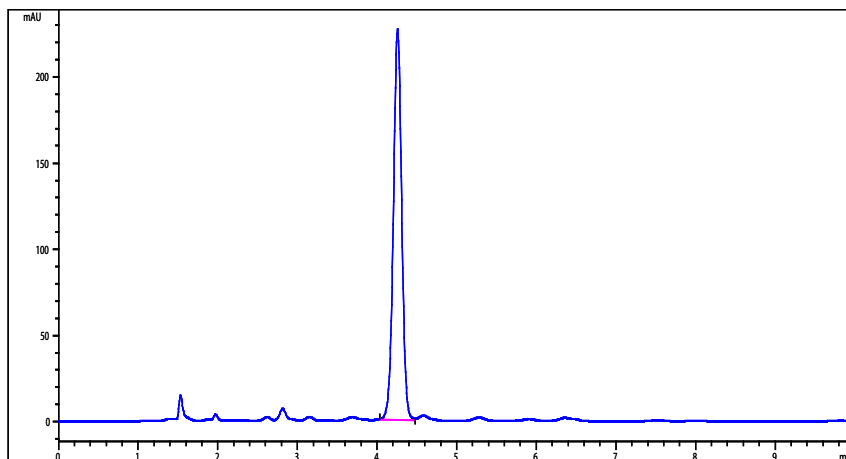
Accurately weigh 0.05 g of the powder in a stoppered conical flask, accurately add 25 mL of 50 % methanol, weigh and treat ultrasonically for 30 minutes, allow to cool, weigh again and replenish the lost weight with 50 % methanol, and mix well. Filter, accurately measure 5 mL of the filtrate in a 25 mL amber volumetric flask, add 50 % methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.4% phosphoric acid (13:87)
- Detector wavelength: 327nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	2.549	4.259	226.89	1659.3	8065	0.98

# Jingzhi guanxin Tablets (*Jingzhi guanxin Pian*) – 精制冠心病片

## Sample source

Commercially available Jingzhi guanxin Tablets

## Chemical reference substances

danshinone IIA (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110766-200214)

## Preparation of test solution

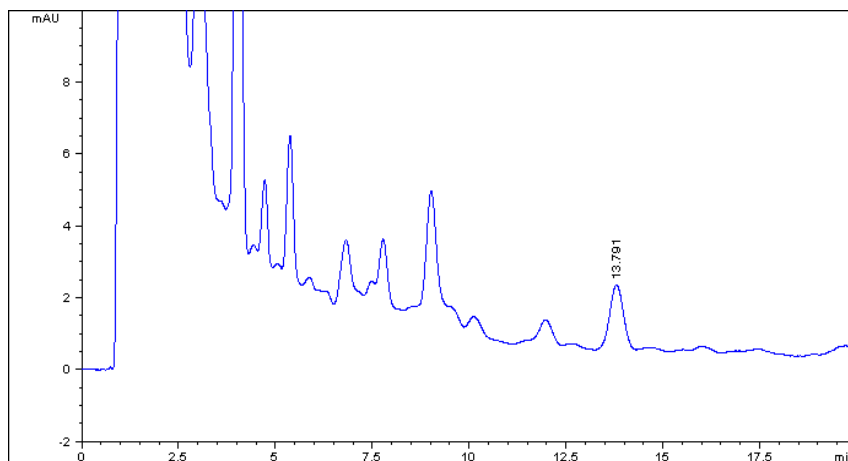
Accurately weigh 10 tablets, remove the coating, grind to a fine powder, accurately weigh 0.2 g of the fine powder in a stoppered conical flask. Accurately add 10 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 15 minutes, allow to cool, weigh again and replenish the lost weight with methanol and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: methanol-water (80:20)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min
- Injection volume: 20  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Danshinone IIA	10.492	13.791	1.80	43.80	7259	0.99

# Jingfukang Granules (*Jingfukang Keli*) – 颈复康颗粒

## Sample source

Commercially available Jingfukang Granules

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110752-200209)

## Preparation of test solution

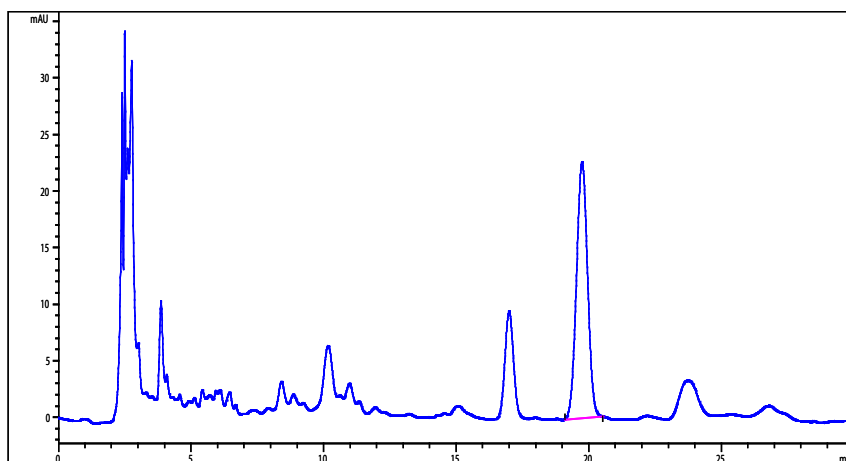
Grind a quantity of the granules to a fine powder and mix well. Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weight again, replenish the lost weight with methanol, shake well. Filter the supernatant through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-0.36% phosphoric acid (23:77)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	6.899	19.748	22.64	659.4	10669	1.03

# Jiuqi Niantong Pills (*Jiuqi Niantong Wan*) – 九气拈痛丸

## Sample source

Commercially available Jiuqi Niantong Pills

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0721-200211)

## Preparation of test solution

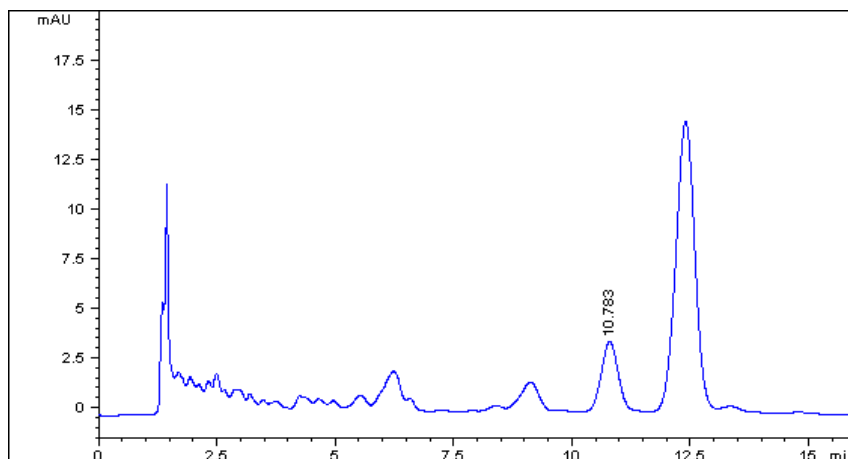
Grind the pills to a fine powder, accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol and stopper tightly. Weigh and allow to soak overnight. Treat ultrasonically for 30 minutes, allow to cool. Weigh again and replenish the lost weight with methanol, mix well. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.5% glacial acetic acid (36:64)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	6.188	10.783	3.50	85.9	4437	1.04

# Jiuwei Qianghuo Pills (*Jiuwei Qianghuo Wan*) – 九味羌活丸

## Sample source

Commercially available Jiuwei Qianghuo Pills

## Chemical reference substances

baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

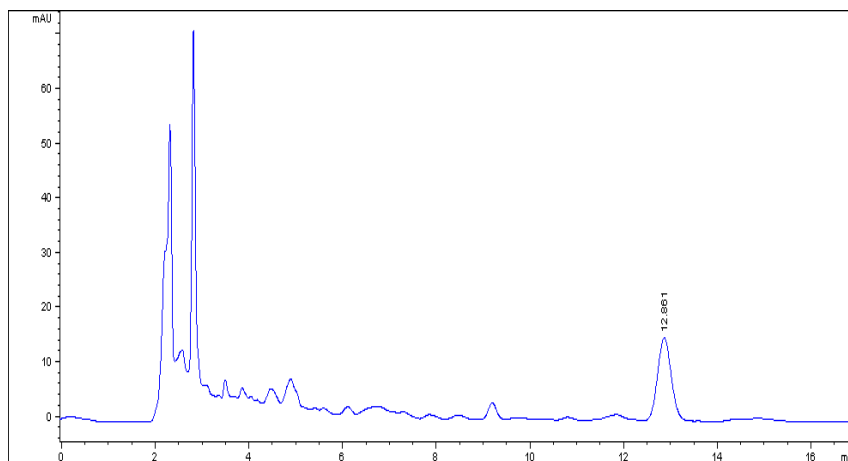
Grind the pills to a fine powder, accurately weigh 0.5 g of the powder, accurately add 50 mL of methanol and weigh. Heat under reflux for 1 hour, allow to cool, weigh again and replenish the lost weight with methanol. Mix thoroughly and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-phosphoric acid (47:53:0.2)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin		12.861	15.22	307.2	9535	1.05

# Red Tangerine Peel (*Exocarpium Citri Rubrum*) – 橘红

## Sample source

Commercially available Red Tangerine Peel

## Chemical reference substances

hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110722-200309)

## Preparation of test solution

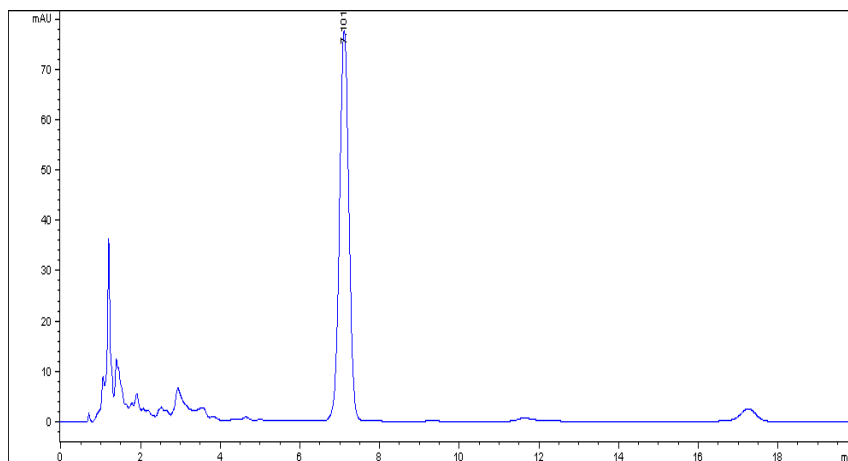
Accurately weigh about 0.2 g of the powder in a conical flask, accurately add 20 mL of methanol, heat and reflux for 1 hour, allow to cool, transfer to a 50 mL volumetric flask, wash the container and the residue with a little methanol for several times, add the washings to the same volumetric flask, add methanol to volume, mix well, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (40:60)
- Detector wavelength: 248 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	4.918	7.101	77.70	1260.8	4510	1.00



# Juhong Tanke Mixture (*Juhong Tanke Ye*) – 橘红痰咳液

## Sample source

Commercially available Juhong Tanke Mixture

## Chemical reference substances

naringin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110722-200309)

## Preparation of test solution

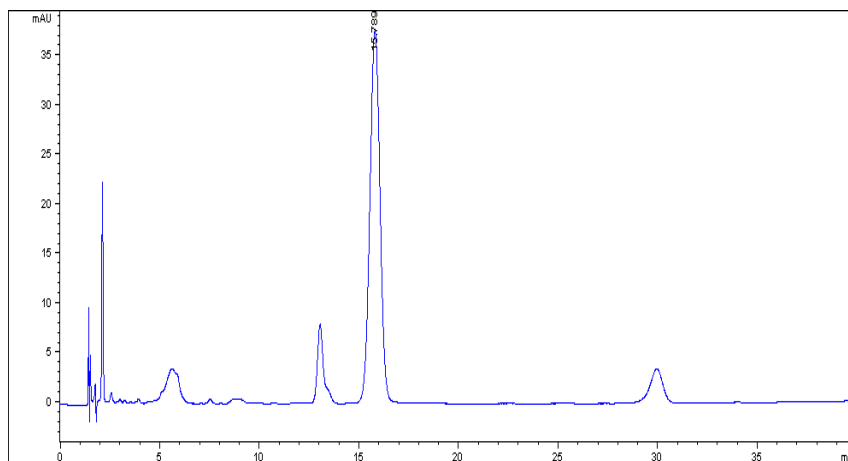
Accurately measure 10 mL of the mixture, extract the mixture with six 10 ml quantities of ethyl acetate by shaking, combine the ethyl acetate extracts, and evaporate to dryness. Dissolve the residue in methanol and transfer to 100 mL volumetric flask, dilute with methanol to volume, mix well, and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid (31:69:3)
- Detector wavelength: 283nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
naringin		15.789	37.61	1321.5	4622	1.00

# Juhong Pills (*Juhong Wan*) – 橘红丸

## Sample source

Commercially available Juhong Pills

## Chemical reference substances

naringin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110722-200309)

## Preparation of test solution

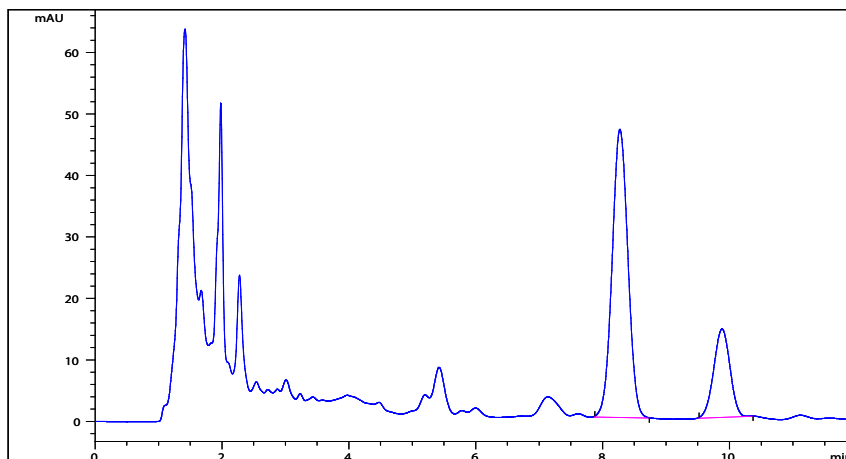
Grind a quantity of pills to a powder, accurately weigh 0.4 g of the powder in a 10 mL volumetric flask, accurately add 10 mL of the mobile phase, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool. Weigh again and replenish the lost weight with the mobile phase, mix well, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-acetic acid-water (33:2:65)
- Detector wavelength: 283nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Naringin	5.894	8.273	46.87	811.2	5322	1.01

# Cassia Seed (*Semen Cassiae*) – 决明子

## Sample source

Commercially available Cassia Seed

## Chemical reference substances

Chrysophanol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110796-200309)

## Preparation of test solution

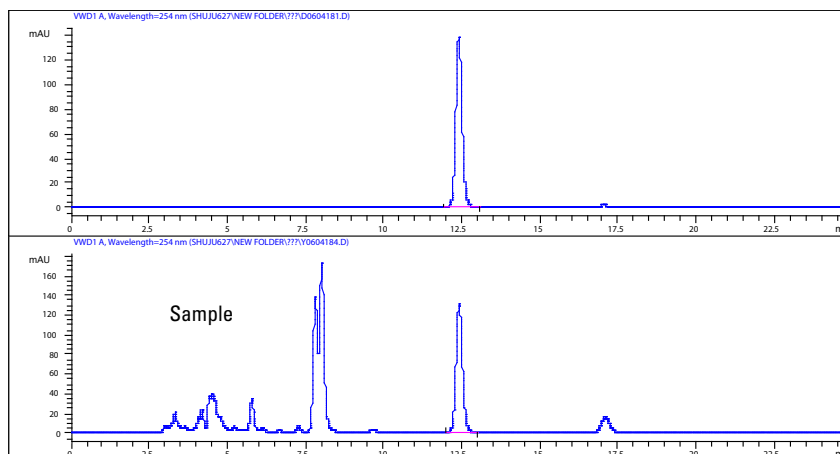
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol and weigh. Heat under reflux for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 25 mL of the filtrate and evaporate the filtrate to dryness. Add 30 mL of 10 % hydrochloric acid to the filtrate. Heat for 1 hour on a water bath and cool immediately. Extract the filtrate with four 30 mL quantities of chloroform. Combine chloroform extracts, evaporate to dryness on a water bath. Dissolve the residue with a mixture of dehydrated ethanol and ethyl acetate (2:1) in a 10 mL volumetric flask. Dilute with the same solvent to volume, mix well, filter, and use the filtrate as test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1 % phosphoric acid (87:13)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	Rs	USP T <sub>r</sub>
Chrysophanol	12.418	130.44	1873.7	18733	8.23	1.06

# Kaixiong Shunqi Pills (*Kaixiong Shunqi Wan*) – 开胸顺气丸

## Sample source

Commercially available Kaixiong Shunqi Pills

## Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110729-200308, 2. 110730-9204)

## Preparation of test solution

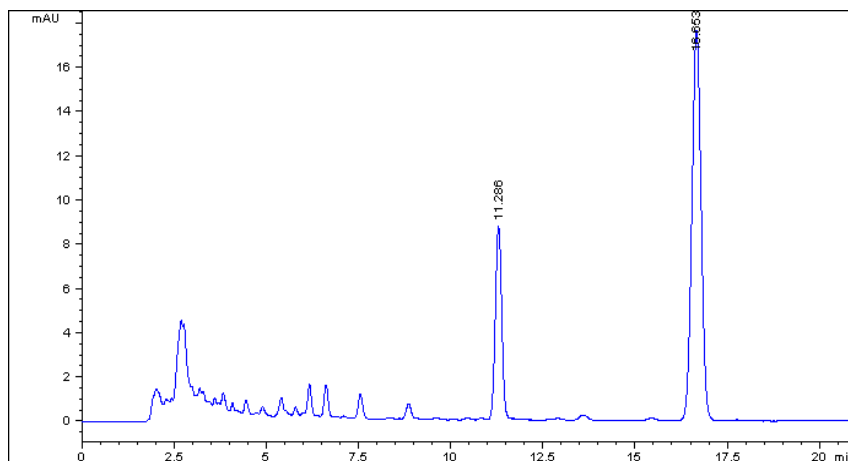
Grind a quantity of the pills to a fine powder. Accurately weigh 2 g in a stoppered conical flask, accurately add 50 mL of methanol and weigh. Treat ultrasonically for 40 minutes and allow to cool. Weigh again and replenish the lost weight with methanol, mix well and filter. Accurately measure 10 mL of the filtrate, evaporate the filtrate to dryness. Dissolve the residue with 20 mL of solution of hydrochloric acid (1:10) in portions, and transfer to a separator. Dissolve the residue with 15 mL of chloroform, in portions, and transfer to the same separator, extract by shaking. Separate the chloroform solution, extract the water solution with two 15 mL quantities of chloroform. Combine the chloroform solution, wash with 20 mL of water. Extract the washings with 10 mL of chloroform. Combine the chloroform extracts, evaporate the solvent to dryness. Dissolve the residue in 90 % methanol, by slightly heating if necessary, and transfer to a 10 mL volumetric flask. Dilute with methanol to volume and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-5% glacial acetic acid (54:46)
- Detector wavelength: 294nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Honokiol	3.514	11.286	8.73	104.3	20746	1.02
Magnolol	5.611	16.653	17.65	305.9	21176	1.00

# Kanggan Granules (*Kanggan Keli*) – 抗感颗粒

## Sample source

Commercially available Kanggan Granules

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

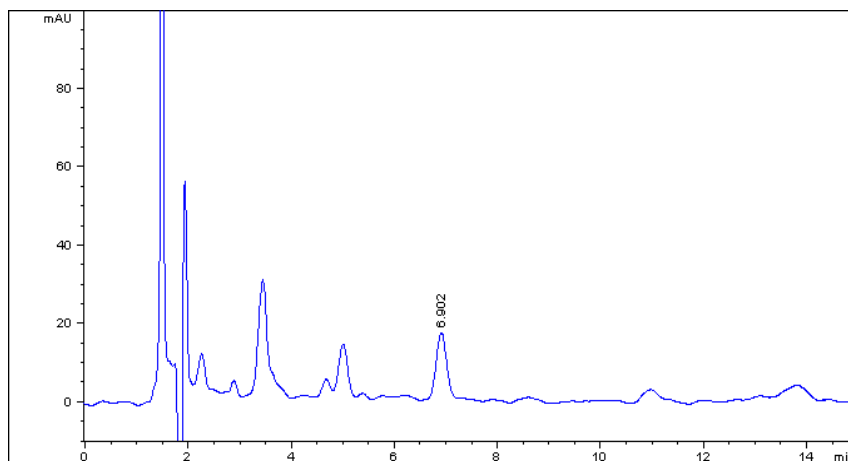
Grind the granules to a fine powder. Accurately weigh 0.6 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol and weigh. Treat ultrasonically for 10 minutes, allow to cool, weigh again and replenish the lost weight with methanol, mix well and filter. Accurately measure 10 mL of the successive filtrate, evaporate the filtrate to dryness. Dissolve the residue in 20 % methanol and transfer to a 10 mL volumetric flask, dilute with 20 % methanol to volume, and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid (30:70:0.5)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	3.602	6.902	16.97	239.4	5565	1.04

# Kanggu Zengsheng Capsules (*Kanggu Zengsheng Jiaonang*)

## 抗骨增生胶囊

### Sample source

Commercially available Kanggu Zengsheng Capsules

### Chemical reference substances

icariine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0737-9910)

### Preparation of test solution

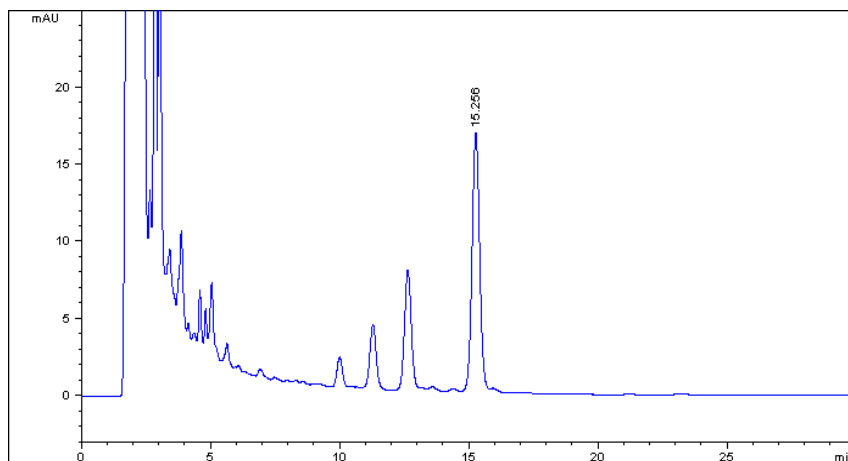
Grind the contents to a fine powder, accurately weigh 1 g in a 100 mL stoppered conical flask, accurately add 50 mL of 50 % ethanol, stopper tightly, and weigh. Treat ultrasonically for 1 hour, allow to cool, weigh again, replenish the lost weight with 50 % ethanol, and shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX XDB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (990967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (25:75)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min
- Injection volume: 3 $\mu\text{L}$

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Icariine		15.256	16.61	331.7	13575	1.04

# Kouyanqing Granules (*Kouyanqing Keli*) – 口炎清颗粒

## Sample source

Commercially available Kouyanqing Granules

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110753-200212)

## Preparation of test solution

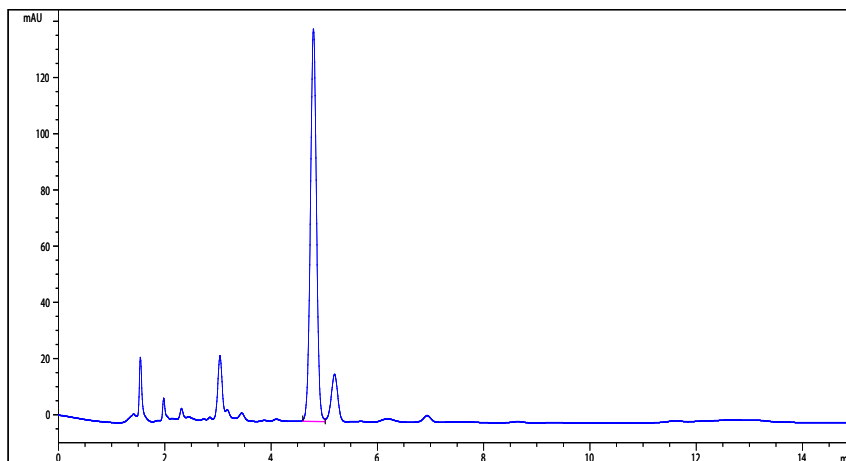
Grind 20 g of the granules to a fine powder, accurately weigh 0.1 g of the powder in a stoppered conical flask, accurately add 10 mL of 50 % methanol. Stopper tightly, allow to stand for 15 minutes, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.4 % phosphoric acid (12:88)
- Detector wavelength: 327nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	2.998	4.798	139.73	1107.7	8662	0.99

# Lightyellow Sophora Root (*Radix sophorae Flavescientis*) – 苦参

## Sample source

Commercially available Lightyellow Sophora Root

## Chemical reference substances

1. Matrine, 2. Oxymatrine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1.110805-200306, 2.110780-200306)

## Preparation of test solution

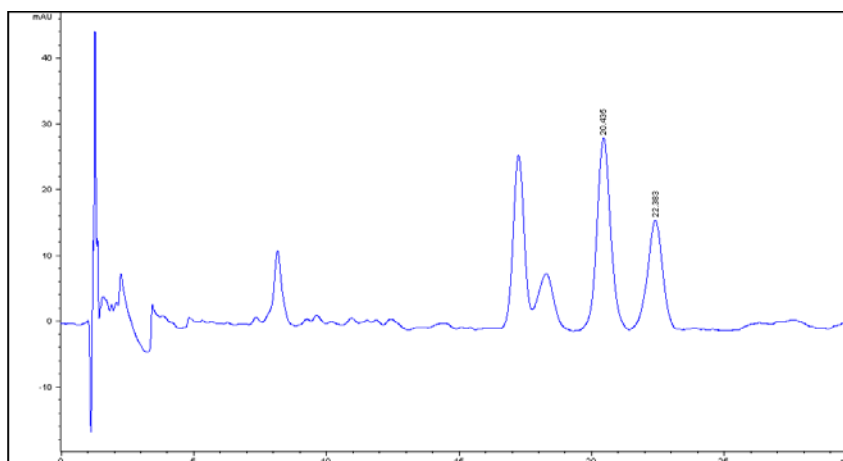
Accurately weigh 0.3 g of the powder in a stoppered conical flask and accurately add 0.5 mL of strong ammonia TS and 20 mL of chloroform, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost solvent with chloroform and mix well, filter. Accurately measure 5 mL of the filtrate and apply to a small column (1 cm in inner diameter) packed with neutral alumina (100-200 mesh, 5 g) and elute with 20 mL quantities of chloroform, a mixture of chloroform and methanol (7:3) successively, collect the eluents and evaporate to dryness. Dissolve the residue with a small quantity of ethanol and transfer to a 10 mL volumetric flask and dilute with ethanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 20 °C
- Mobile phase: acetonitrile-methanol-0.05 % phosphoric acid (1.5 % sodium dodecylsulphate) (30:10:60)
- Detector wavelength: 220 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Matrine	13.922	22.383	16.56	653.6	7710	0.94
Oxymatrine	12.623	20.435	29.20	1043.7	8133	1.07



# Lidan Paishi Tablets (*Lidan Paishi Pian*) – 利胆排石片

## Sample source

Commercially available Lidan Paishi tablets

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

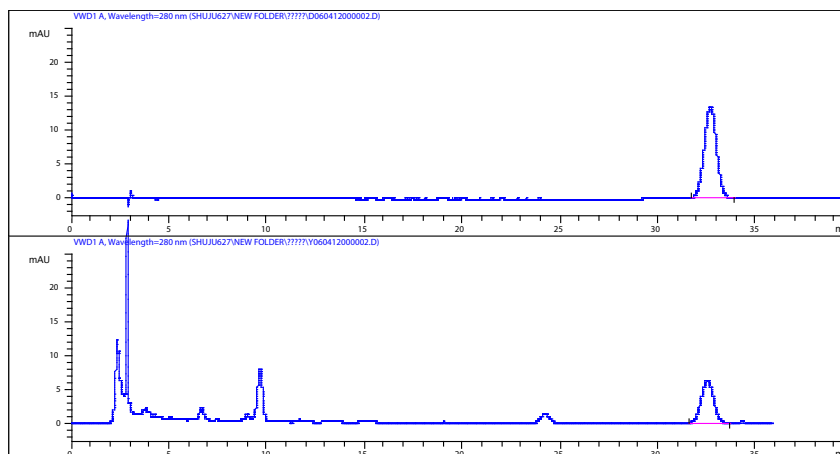
Accurately weigh 20 tablets, remove the coating and grind to a fine powder. Accurately weigh 0.5 g in a stoppered conical flask, accurately add 50 mL of 70 % ethanol and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again and replenish the lost weight with 70 % ethanol, mix well and filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with 70 % ethanol to volume, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Eclipse Plus C18 4.6×250 mm, 5 µm (959990-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.5% phosphoric acid (40:60)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	Rs	USP T <sub>r</sub>
Baicalin	32.529	6.34	278.6	12697	8.34	0.98

# Weeping Forsythia Extract (*Extractum Forsythiae Siccus*)

## 连翘提取物

### Sample source

Commercially available Weeping Forsythia Extract

### Chemical reference substances

Forsythin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110821-200305)

### Preparation of test solution

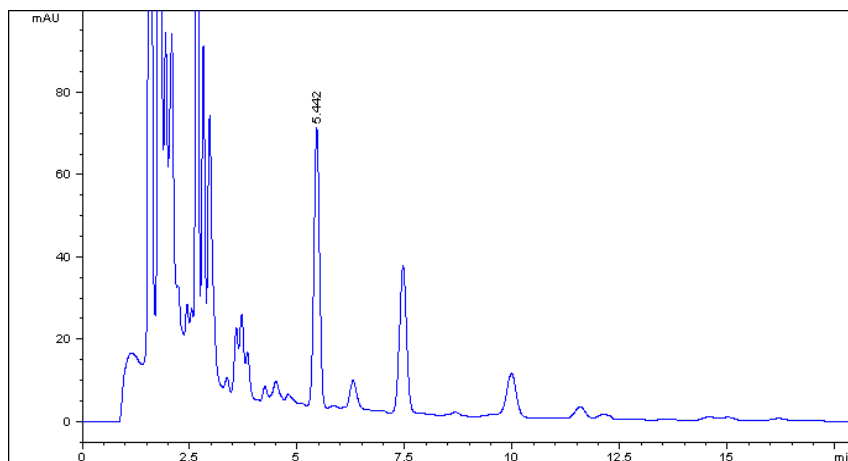
Accurately weigh 1.0 g in a stoppered conical flask, accurately add 15 mL of methanol, and weigh. Allow to stand overnight, treat ultrasonically for 25 minutes, allow to cool, weigh again, replenish the lost weight with methanol, shake well and filter. Accurately measure 5 mL of the filtrate, evaporate to near dryness, and mix well with 0.5 g of neutral alumina and then transfer to a neutral alumina column (100-200 mesh). Elute with 120 mL of 70 % ethanol, collect the eluents, and concentrate to dryness. Dissolve the residue in 50 % methanol in a 10 mL volumetric flask, add 50 % methanol to volume, shake well and filter.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (24:76)
- Detector wavelength: 277 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Forsythin	2.628	5.442	67.62	606.2	8677	0.98

# Lingyang Ganmao Tablets (*Lingyang Ganmao Pian*) – 羚羊感冒片

## Sample source

Commercially available Lingyang Ganmao Tablets

## Chemical reference substances

Arctiin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0819-9802)

## Preparation of test solution

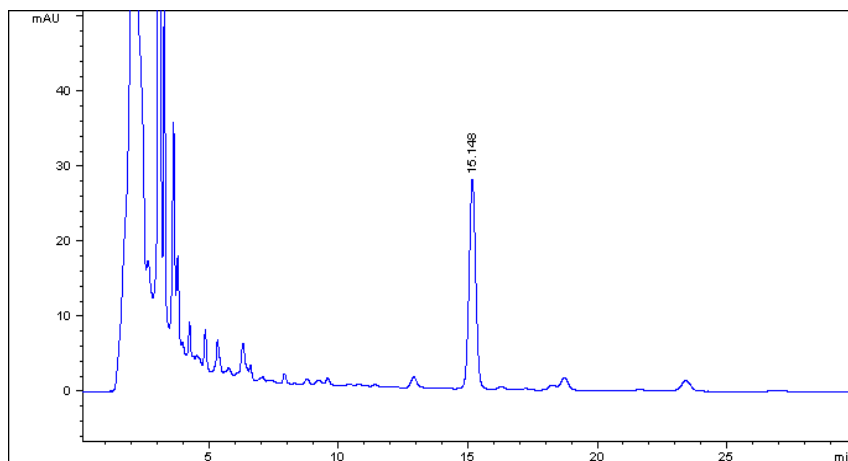
Grind 10 tablets to a fine powder and remove the coating. Accurately weigh 0.25 g of the powder in a stoppered conical flask, accurately add 20 mL of 50 % methanol, stopper tightly, and weigh. Treat ultrasonically for 20 minutes, allow to cool, and weigh again. Replenish the lost weight with 50 % methanol, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (25:75)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Arctiin	5.059	15.148	27.93	497.6	17210	1.03

# Lingyang Qingfei Pills (*Lingyang Qingfei Wan*) – 羚羊清肺丸

## Sample source

Commercially available Lingyang Qingfei Pills

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110753-200212)

## Preparation of test solution

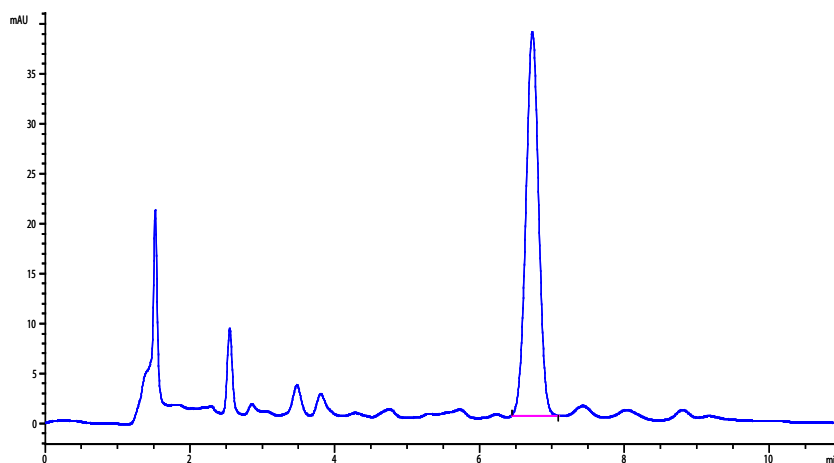
Grind the pills. Accurately weigh 0.4 g in a stoppered conical flask, accurately add 10 mL of 70 % methanol, stopper tightly and weigh. Treat ultrasonically for 40 minutes, allow to cool, weigh again and replenish the lost weight with 70 % methanol, mix well and filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 40  $^{\circ}\text{C}$
- Mobile phase: methanol-water-phosphoric acid (20:80:0.1)
- Detector wavelength: 327nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	4.609	6.731	38.45	471.4	7189	0.99

# Liuwei Dihuang Pills (*Liuwei Dihuang Wan*) – 六味地黄丸

## Sample source

Commercially available Liuwei Dihuang Pills

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110708-200205)

## Preparation of test solution

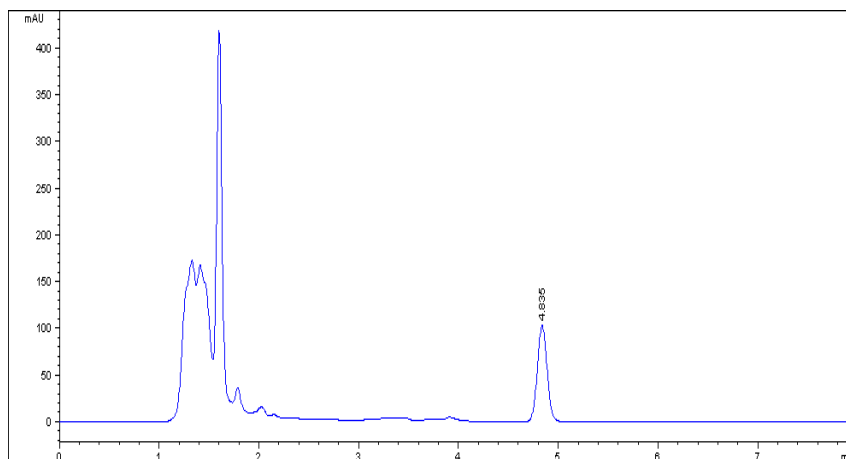
Grind the pills to a fine powder and mix well. Accurately weigh 0.3 g of the powder in a stoppered conical flask, accurately add 50 mL of 50 % methanol, stopper tightly, and weigh. Treat ultrasonically for 45 minutes, allow to cool. Weigh again and replenish the lost weight with 50 % methanol, mix well and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (60:40)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	2.223	4.835	103.29	704.5	12176	1.05

# Liuwei Dihuang Pills (*Liuwei Dihuang Wan*) – 六味地黄丸

## Sample source

Commercially available Liuwei Dihuang Pills

## Chemical reference substances

Loganin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111640-200401)

## Preparation of test solution

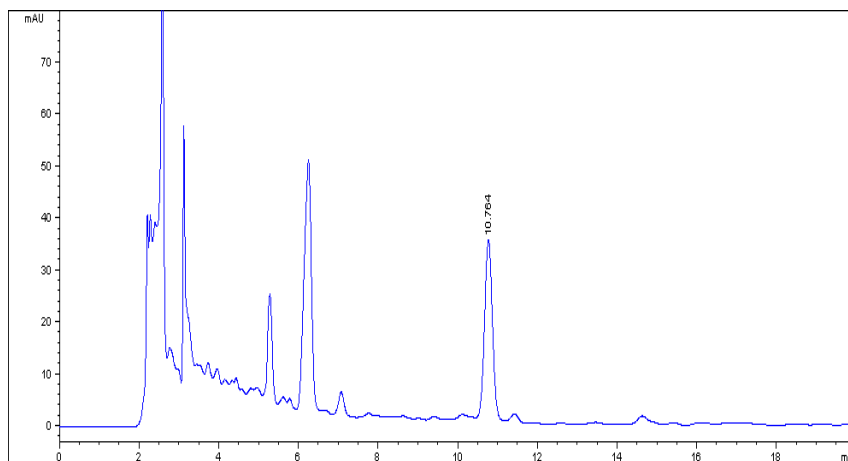
Grind the pills to a fine powder, mix well. Accurately weigh 0.7 g of the powder in a stoppered conical flask, accurately add 25 mL of 50 % methanol, stopper tightly, and weigh. Treat ultrasonicate for 15 minutes, heat under reflux for 1 hour and allow to cool. Weigh again and replenish the lost weight with 50 % methanol, mix well and filter. Accurately measure 10 mL of the filtrate, apply to a column (1 cm in internal diameter) packed with neutral alumina (100-200 mesh, 4 g). Elute with 50 mL of 40 % methanol, collect the eluent. Evaporate to dryness and dissolve the residue in a quantity of 50 % methanol, transfer to a 10 mL volumetric flask, dilute with 50 % methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-methanol-tetrahydro-furan-0.05% phosphoric acid (8:4:1:87)
- Detector wavelength: 236 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Loganin	3.306	10.764	34.47	471.3	14401	1.00

# Liuying Pills (*Liuying Wan*) – 六应丸

## Sample source

Commercially available Liuying Pills

## Chemical reference substances

1. Bufogenin, 2. Cinobufagin  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1.803-200203, 2.718-200207)

## Preparation of test solution

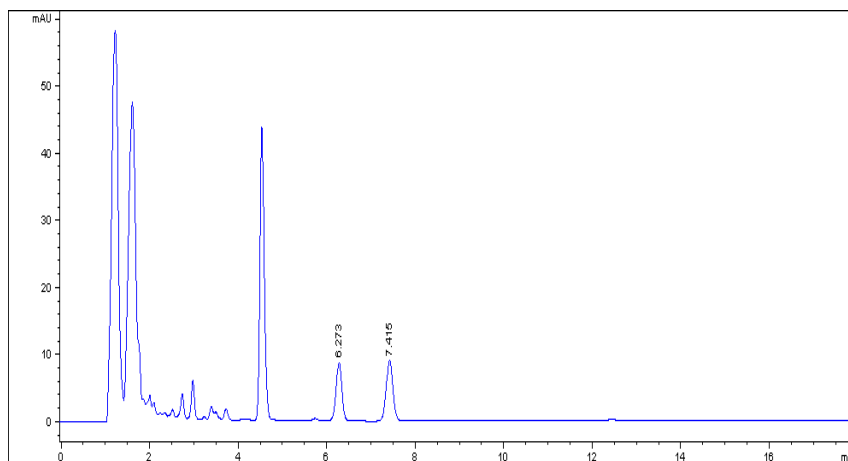
Grind a quantity of the pills to a powder, accurately weigh 0.3 g of the powder, accurately add 20 mL of methanol, heat under reflux for 1.5 hours, allow to cool. Weigh again and replenish the lost weight with methanol, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.5% potassium dihydrogen phosphate (50:50)
- Detector wavelength: 296nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Cinobufagin	4.227	6.273	8.65	78.1	11391	0.97
Bufogenin	5.179	7.415	9.01	95.4	11654	1.00

# Longdan Xiegan Pills (*Longdan Xiegan Wan (Shuiwan)*)

## 龙胆泻肝丸 (水丸)

### Sample source

Commercially available Longdan Xiegan Pills (Water Pills)

### Chemical reference substances

Gentioicrin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110770-200308)

### Preparation of test solution

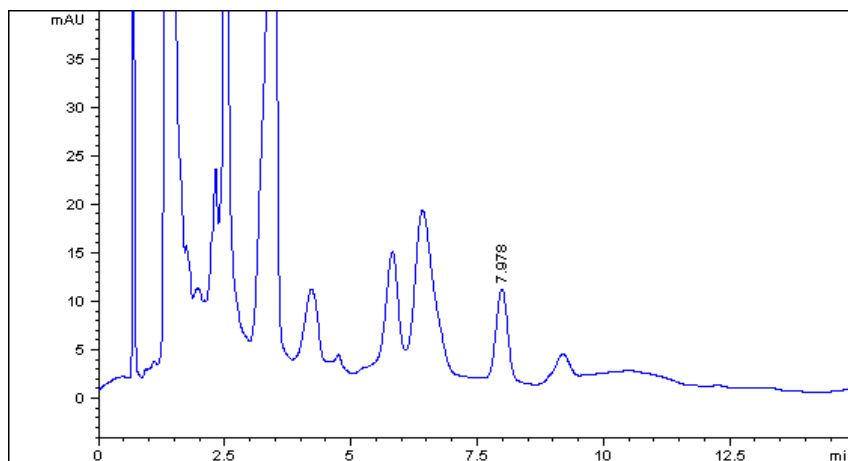
Grind a quantity of granules to a fine powder. Accurately weigh 1 g of the powder in a stoppered conical flask and accurately add 25 mL of methanol, and weigh. Treat ultrasonically for 45 minutes, allow to cool. Weigh again and replenish the lost weight with methanol, mix well and filter, use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 40 °C
- Mobile phase: methanol-water (21:79)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Gentioicrin	4.319	7.978	9.41	150.0	5796	0.95



# Longqing Tablets (*Longqing Pian*) – 癭清片

## Sample source

Commercially available Longqing Tablets

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

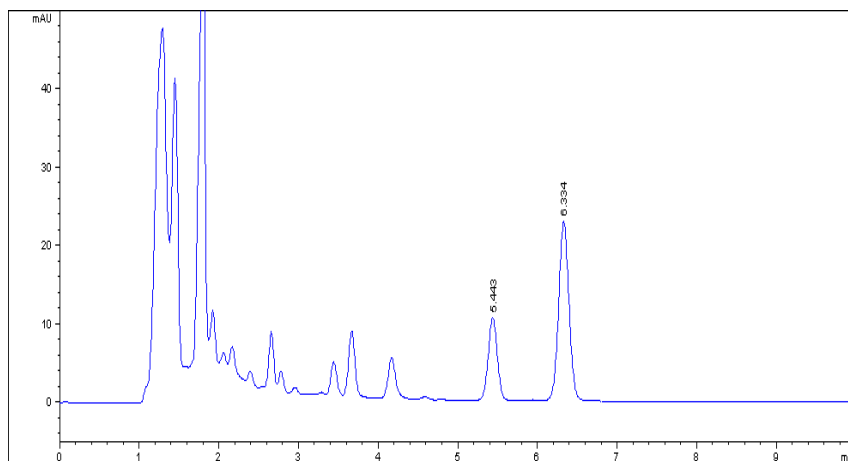
Accurately weigh 20 tablets, grind to a fine powder, accurately weigh 0.1 g of the fine powder in a stoppered conical flask, accurately add 50 mL of dilute ethanol TS, stopper tightly and weigh, treat ultrasonically for 30 minutes, allow to cool, weigh again and replenish the lost weight with dilute ethanol TS, mix well, filter. Use the filtrate as the test solution

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.05mol/L sodium dihydrogen phosphate (adjust the pH to 3 with phosphoric acid)(30:70)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Berberine	3.222	6.334	22.91	205.3	11899	1.04

# Aloes (*Aloe*) – 芦荟

## Sample source

Commercially available Aloes

## Chemical reference substances

barbaloin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0787-200303)

## Preparation of test solution

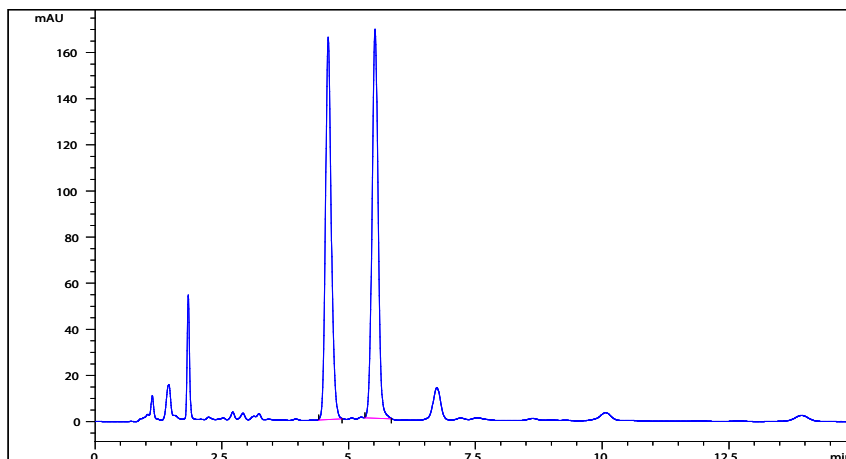
Accurately weigh 0.025 g of the powder in a 25 mL volumetric flask, add a quantity of methanol, treat ultrasonically for 30 minutes, allow to cool, add methanol to volume, mix well, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (25:75)
- Detector wavelength: 355 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Barbaloin	3.602	5.522	168.67	1406.2	10610	1.03

# Lusika Pills (*Lusika Wan*) – 鹭鸶咯丸

## Sample source

Commercially available Lusika Pills

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110749-200309)

## Preparation of test solution

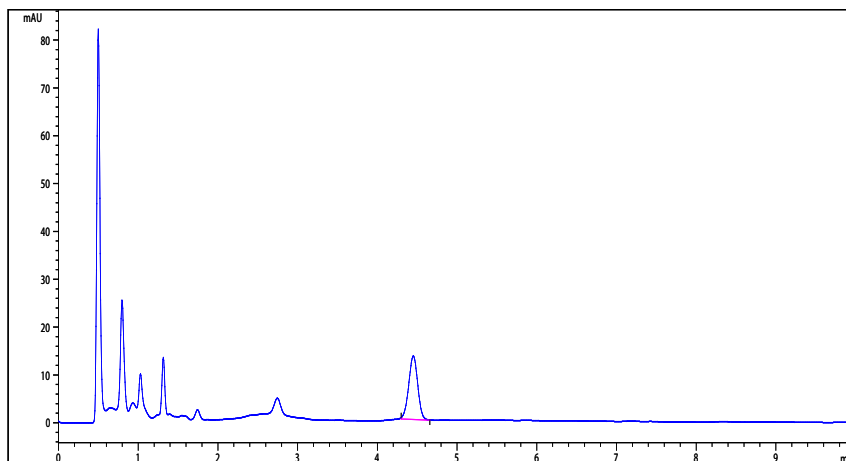
Grind a quantity of the pills. Accurately weigh 0.1 g in a stoppered conical flask and accurately add 10 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool. Weigh again and replenish the lost weight with methanol, mix well and filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (12:88)
- Detector wavelength: 238nm
- Flow rate: 1.5 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide	4.564	4.451	13.26	103.9	7456	0.96

# Dogbane Leaf (*Folium Apocyni Veneti*) – 罗布麻叶

## Sample source

Commercially available Dogbane Leaf

## Chemical reference substances

Quercetin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0081-9905)

## Preparation of test solution

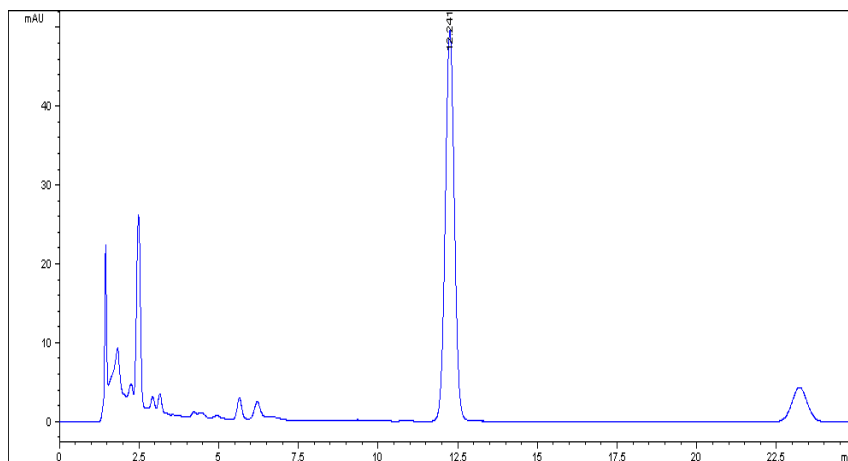
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of 80 % methanol, weigh, heat under reflux on a water bath for 1 hour, cool, weigh again, replenish the lost weight with 80 % methanol, mix well and filter. Accurately measure 10 mL of the filtrate, add 1 mL of hydrochloric acid, heat under reflux on a water bath at 90 °C for 60 minutes, cool immediately, transfer to a 25 mL volumetric flask, dilute with 80 % methanol to volume, mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-906)
- Column temperature: 30 °C
- Mobile phase: methanol-0.4 % phosphoric acid (45:55)
- Detector wavelength: 360 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Quercetin	7.160	12.241	48.77	984.4	8740	1.02

# Ephedra Herb (*Herba Ephedrae*) – 麻黄

## Sample source

Commercially available Ephedra

## Chemical reference substances

Ephedrine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

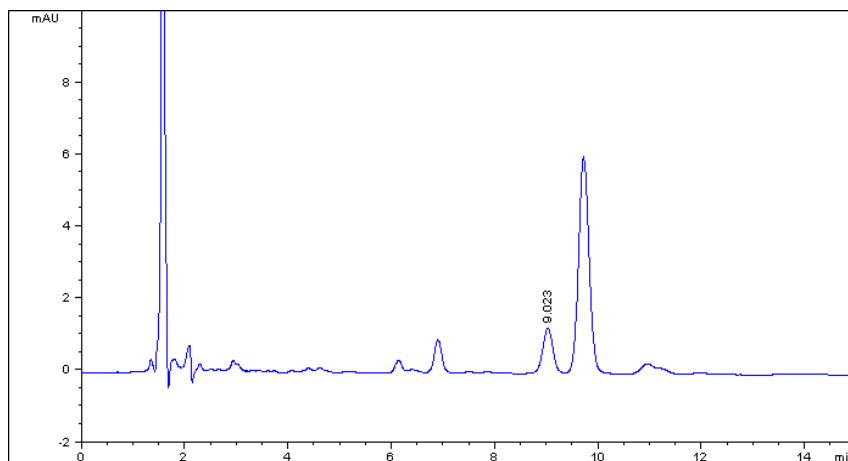
Accurately weigh 0.2 g of the fine powder in a stoppered conical flask, accurately add 25 mL of methanol, weigh, treat ultrasonically for 45 minutes, allow to cool, weigh again and replenish the lost weight with methanol, shake well and filter. Accurately apply 1 mL of the successive filtrate to a small column (1 cm in inner diameter) packed with neutral aluminium oxide (100-200 mesh, 1.5 g), elute with 50 % methanol. Collect about 9 mL of the eluent in a 10 mL volumetric flask, add 1 drop of phosphoric acid, dilute with 50 % methanol to volume, and mix well. Filter through a millipore membrane (0.45 µm), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.1% phosphoric acid (6:94)
- Detector wavelength: 207 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ephedrine	5.015	9.023	1.26	17.4	10356	1.0

# Maren Runchang Pills (*Maren Runchang Wan*) – 麻仁润肠丸

## Sample source

Commercially available Maren Runchang Pills

## Chemical reference substances

1. Emodin, 2. Chrysophanol  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110756-200210, 2. 110796-200309)

## Preparation of test solution

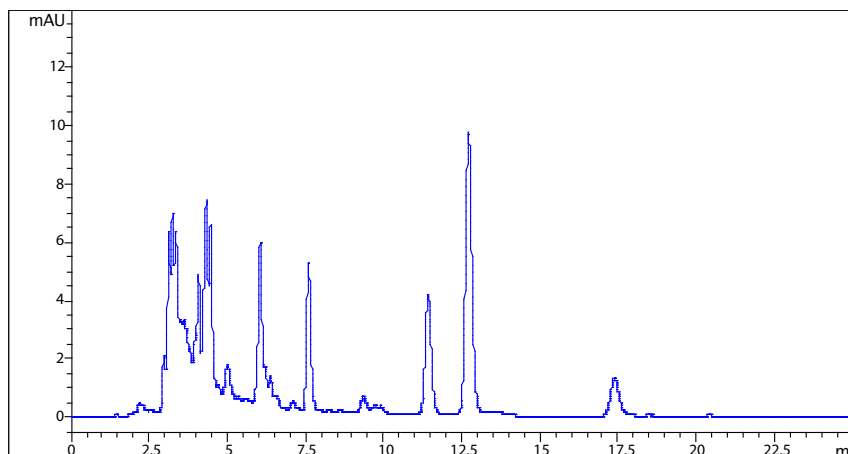
Cut a quantity of the pills into pieces. Accurately weigh 1 g, grind well with 1.5 g of kieselguhr, transfer to a Soxhlet extractor, add a quantity of ethanol, and heat under reflux to the extract colorless. Transfer the extract solution to a 50 mL volumetric flask, dilute to volume with ethanol and shake well. Accurately measure 10 mL of the solution in a flask, and evaporate to near dryness on a water bath. Add 15 mL of a mixture of hydrochloric acid and 30 % solution of methanol (1:10), heat on a water bath for 1 hour, and cool immediately. Extract the solution with four 15 mL quantities of chloroform by shaking, combine the chloroform solution, and evaporate to dryness. Dissolve the residue in a quantity of methanol, transfer to a 10 mL volumetric flask, dilute to volume, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (518925-902)
- Column temperature: 27  $^{\circ}\text{C}$
- Mobile phase: methanol-0.1% phosphoric acid (80:20)
- Detector wavelength: 254nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	11.424	4.03	53.5	17823	1.06
Chrysophanol	12.721	9.54	134.0	19659	1.07

# Maren Pills (*Maren Wan*) – 麻仁丸

## Sample source

Commercially available Maren Pills

## Chemical reference substances

1. Emodin, 2. Chrysophanol  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 110756-200210, 2. 110796-200309)

## Preparation of test solution

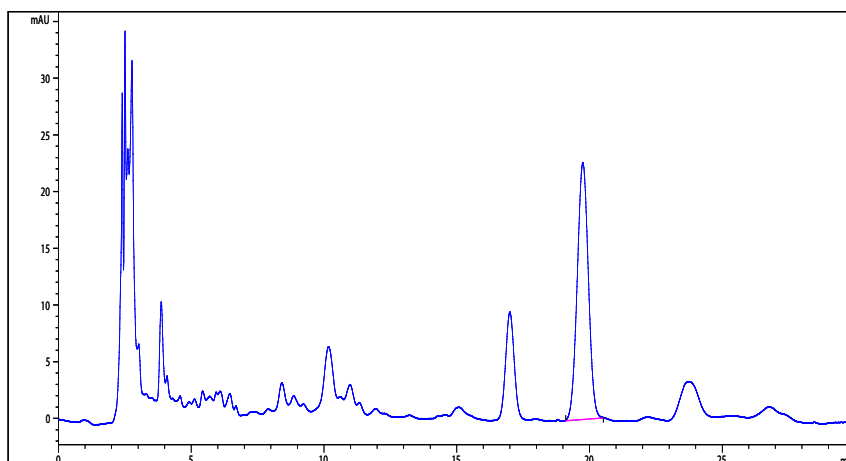
Grind a quantity of the pills to a fine powder. Accurately weigh 0.8 g of the powder, transfer to a Soxhlet extractor, add a quantity of ethanol, and heat under reflux until the extract is colorless. Evaporate the extract to dryness on a water bath. Add 15 mL of a mixture of 30 % solution of methanol and hydrochloric acid (10:1), heat on a water bath for 50 minutes, and cool immediately. Extract the solution with five 15 mL quantities of chloroform by shaking, combine the chloroform solution, and evaporate to dryness. Dissolve the residue with a mixture of dehydrated ethanol and ethyl acetate (2:1), transfer to a 25 mL volumetric flask, dilute to volume, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6× 250 mm, 5 μm (518925-902)
- Column temperature: 27 °C
- Mobile phase: methanol-0.1% phosphoric acid (80:20)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	11.393	17.20	231.7	17306	3.57	1.0
Chrysophanol	12.704	54.86	778.8	19169	3.57	1.07

# Maiwei Dihuang Pills (*Maiwei Dihuang Wan*) – 麦味地黄丸

## Sample source

Commercially available Maiwei Dihuang Pills

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0708-9704)

## Preparation of test solution

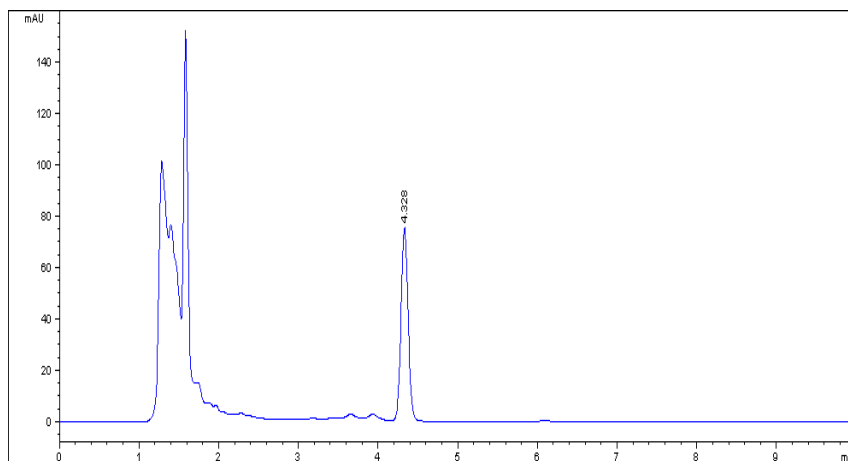
Grind the pills to a fine powder and mix well. Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of 50 % methanol, stopper tightly, and weigh. Treat ultrasonically for 45 minutes, allow to cool. Weigh again and replenish the lost weight with 50 % methanol, mix well and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (62:38)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Paeonol	1.885	4.328	75.26	464.1	11584	1.05



# Maiwei Dihuang Pills (*Maiwei Dihuang Wan*) – 麦味地黄丸

## Sample source

Commercially available Maiwei Dihuang Pills

## Chemical reference substances

Loganin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111640-200205)

## Preparation of test solution

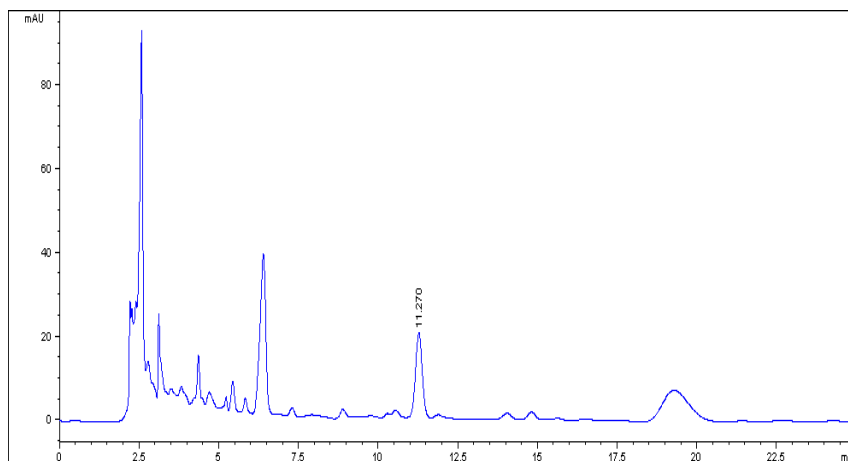
Grind the pills to a fine powder and mix well. Accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 25 mL of 50 % methanol, stopper tightly, and weigh. Treat ultrasonically for 15 minutes, heat under reflux for 1 hour and cool. Weigh again and replenish the lost weight with 50 % methanol, mix well and filter. Accurately measure 10 mL of the filtrate, apply to a column (1 cm in internal diameter) packed with neutral alumina (100-200 mesh, 4 g). Elute with 50 mL of 40 % methanol, collect the eluent. Evaporate to dryness and dissolve the residue in a quantity of 50 % methanol, transfer to a 5 mL volumetric flask, dilute with 50 % methanol to volume, and mix well. Filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-methanol-tetrahydro-furan-0.05% phosphoric acid (8:4:1:87)
- Detector wavelength: 236nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Loganin	3.508	11.270	20.24	298.1	13816	1.00

# Shrub Chasetree Fruit (*Fructus Viticis*) – 蔓荆子

## Sample source

Commercially available Shrub Chastetree Fruit

## Chemical reference substances

Vitexicarpin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1554-200101)

## Preparation of test solution

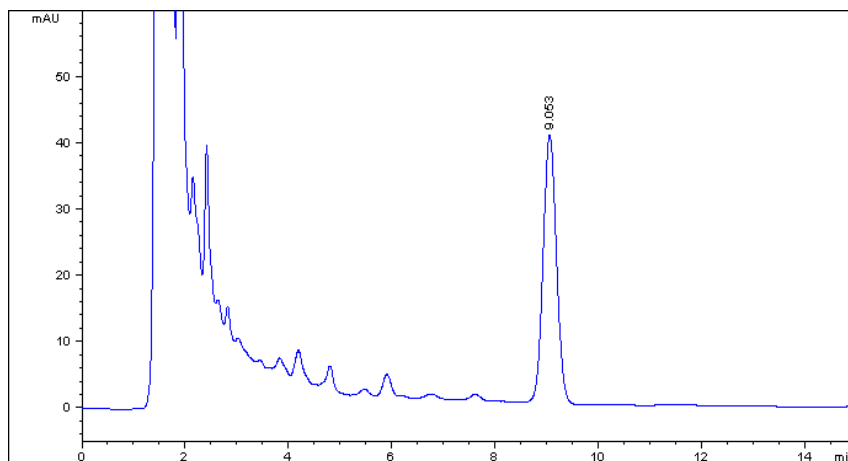
Accurately weigh 2 g of the powder in a stoppered conical flask. Accurately add 50 mL of methanol, weigh, and heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.4% phosphoric acid (60:40)
- Detector wavelength: 258nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Vitexicarpin	5.035	9.053	40.44	723.1	5933	1.04

# Meihua Dianshe Pills (*Meihua Dianshe Wan*) – 梅花点舌丸

## Sample source

Commercially available Meihua Dianshe Pills

## Chemical reference substances

Cinobufagin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110803-200203)

## Preparation of test solution

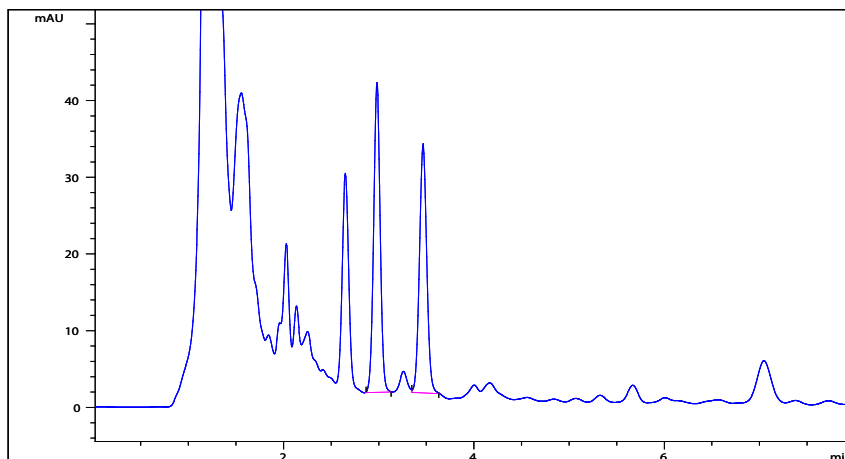
Grind the pills to a fine powder and accurately weigh 0.06 g in a 5 mL volumetric flask. Add 4 mL of methanol, treat ultrasonically for 30 minutes, allow to cool, dilute to volume with methanol, shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (65:35)
- Detector wavelength: 296nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Cinobufagin	1.484	2.981	40.39	193.3	9287	1.02

# Mingmu Dihuang Pills (*Mingmu Dihuang Wan*) – 明目地黄丸

## Sample source

Commercially available Mingmu Dihuang Pills

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110708-200205)

## Preparation of test solution

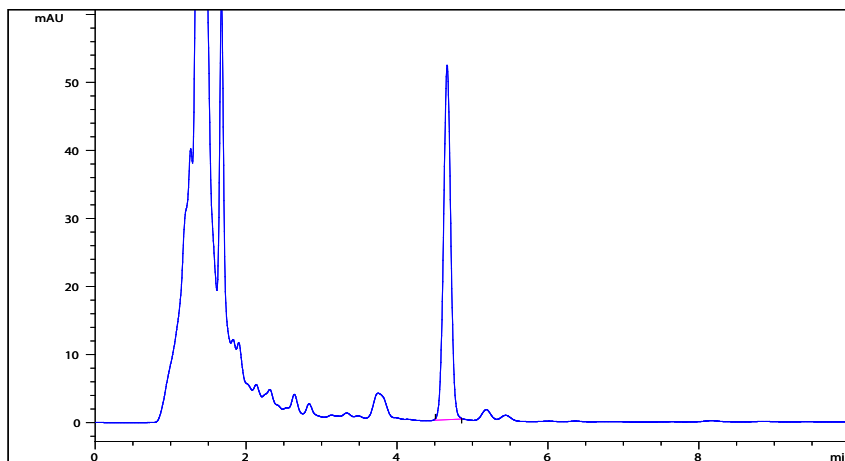
Cut the pills into pieces, accurately weigh 0.5 g in a stoppered conical flask, accurately add 50 mL of 70 % methanol, stopper tightly and weigh. Treat ultrasonically for 45 minutes, cool, weigh again, replenish the lost weight with 70 % methanol and shake well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (70:30)
- Detector wavelength: 274nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	2.888	4.665	52.11	345.8	11890	0.98

# Mingmu Dihuang Pills (*Mingmu Dihuang Wan*) – 明目地黄丸

## Sample source

Commercially available Mingmu Dihuang Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

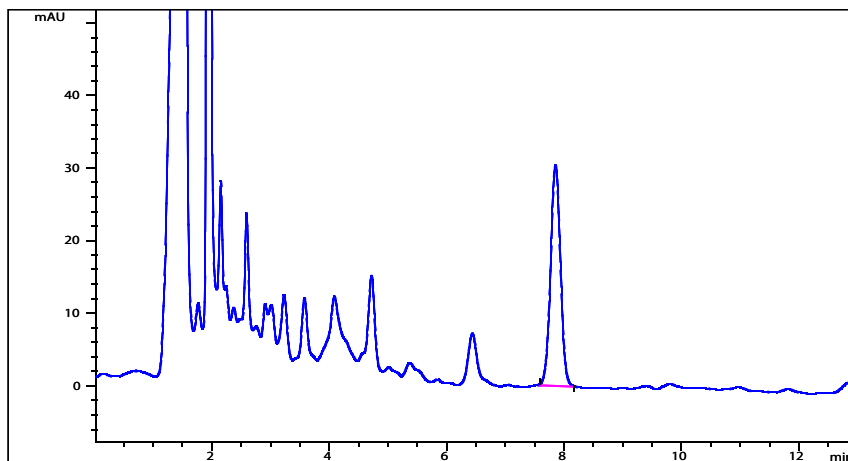
Cut the pills into pieces, accurately weigh 0.5 g, accurately add 50 mL of 70 % methanol, stopper tightly and weigh. Treat ultrasonically for 45 minutes, allow to cool, weigh again, replenish the lost weight with 70 % methanol and shake well. Accurately measure 25 mL of the solution and evaporate to dryness. Dissolve the residue in 25 mL of water by warming, allow to cool, extract with three 25 mL quantities of n-butanol and evaporate to dryness. Dissolve the residue in methanol and transfer to a 5 mL volumetric flask, add methanol to volume and shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.1% phosphoric acid (14:86)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	5.549	7.858	30.40	355.0	10803	0.99

# Tree Peony Bark (*Cortex Moutan*) – 牡丹皮

## Sample source

Commercially available Tree Peony Bark

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110708-200205)

## Preparation of test solution

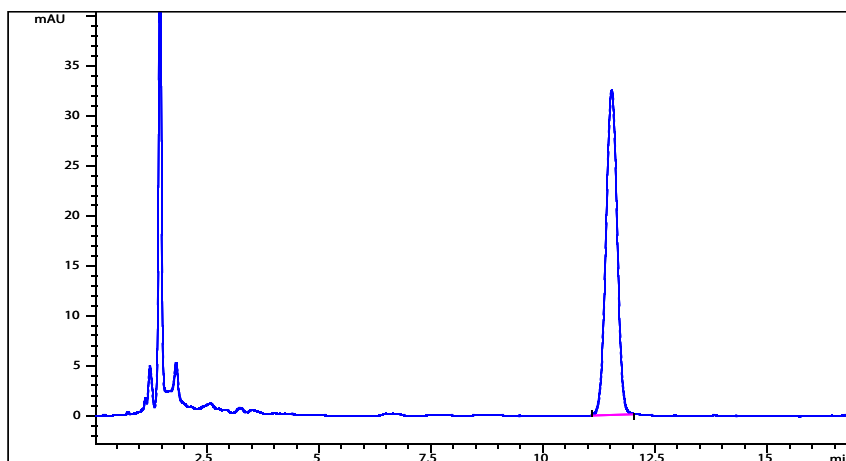
Accurately weigh 0.05 g of the powder in a stoppered conical flask, accurately add 10 mL of methanol, mix well, weigh, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well, filter. Accurately measure 1 mL of the filtrate in a 10 mL volumetric flask, add methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (45:55)
- Detector wavelength: 274nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	8.612	11.534	32.46	562.7	10158	0.99

# Clove Fruit (*Fructus Caryophylli*) – 母丁香

## Sample source

Commercially available Clove Fruit (Beijing)

## Chemical reference substances

Eugenol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110725-200209)

## Preparation of test solution

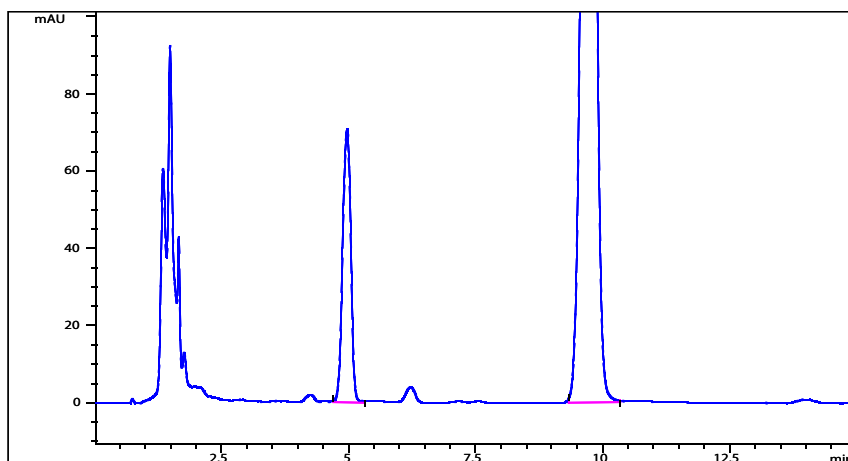
Accurately weigh 0.3 g of the powder in a 25 mL volumetric flask, add dehydrated ethanol to volume, and allow to soak for 24 hours. Mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (13:8)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Eugenol	3.140	4.968	70.90	798.1	4317	0.96

# Common Aucklandia Root (*Radix Aucklandiae*) – 木香

## Sample source

Commercially available Common Aucklandia Root

## Chemical reference substances

1. Costunolide, 2. Dehydrocostus-lactone (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 111524-200101, 2. 111525-200103)

## Preparation of test solution

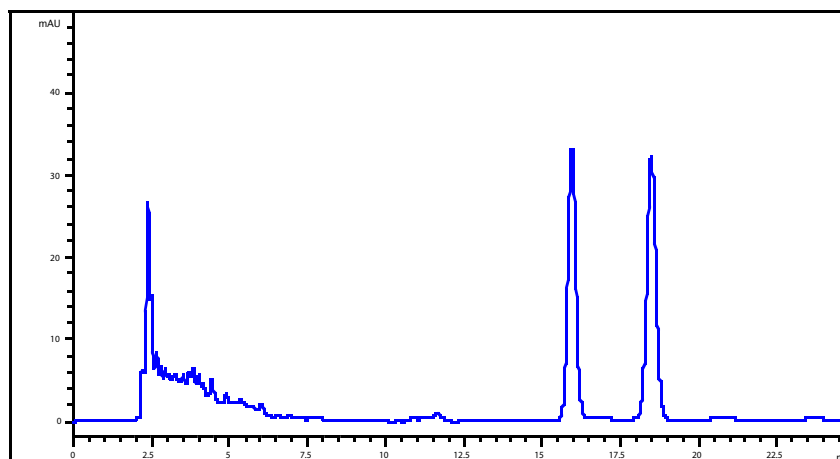
Accurately weigh 0.3 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly and weigh. Allow to soak overnight, treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost weight with methanol, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Eclipse Plus C18, 4.6×250 mm, 5 µm (959990-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (65:35)
- Detector wavelength: 225 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Rs	n	USP T <sub>r</sub>
Costunolide	15.946	33.08		18464	1.02
Dehydrocostus- lactone	18.491	31.37	5.0	19368	1.02



# Common Scouring Rush Herb (*Herba Equiseti Hiemalis*) – 木 賊

## Sample source

Commercially available Common Scouring Rush Herb

## Chemical reference substances

Kaempferol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0864-9901)

## Preparation of test solution

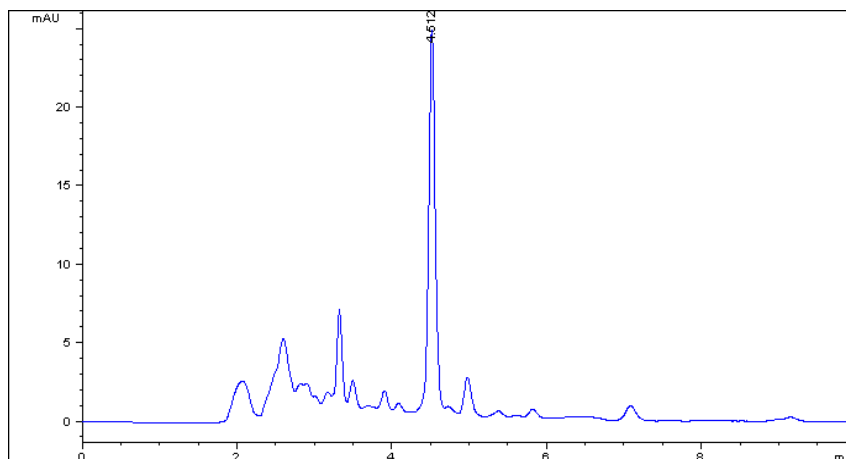
Accurately weigh 0.75 g of the powder in a stoppered conical flask, accurately add 50 mL of 75 % methanol, weigh, heat on a water bath for 1 hour, allow to cool, weigh again, replenish the lost weight with 75 % methanol, mix well and filter. Accurately measure 20 mL of the filtrate, accurately add 5 mL of hydrochloric acid, heat on a water bath for 1 hour, and allow to cool. Transfer to a 50 mL volumetric flask, dilute with 75 % methanol to volume and mix well, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 30 °C
- Mobile phase: acetonitrile-0.4% phosphoric acid (52:48)
- Detector wavelength: 365 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Kaempferol	0.805	4.512	24.18	140.1	15456	1.05

# Naodesheng Tablets (*Naodesheng Pian*) – 脑得生片

## Sample source

Commercially available Naodesheng Tablets

## Chemical reference substances

1. Ginsenoside Rg1, 2. Ginsenoside Rb1, 3. Notoginsenoside R1 (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1.110703-200322, 2.0704-9710, 3.110745-200312)

## Preparation of test solution

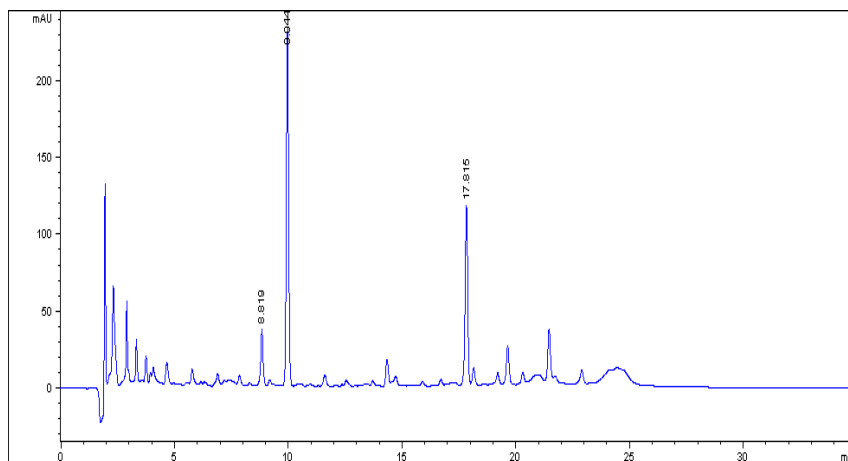
Remove the coating from 20 tablets, accurately weigh, grind well, accurately weigh 1 g in a stoppered conical flask, accurately add 50 mL of n-butanol saturated with water, stopper tightly and weigh. Treat ultrasonically for 20 minutes, allow to cool, weigh again, replenish the lost weight with n-butanol saturated with water, shake well and filter. Accurately measure 25 mL of the filtrate in a separating funnel, and wash twice with ammonia TS (15 ml, 10 ml). Evaporate the n-butanol solution to dryness, dissolve the residue in methanol, transfer to a 5 mL volumetric flask, add methanol to volume and shake well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 25 °C
- Mobile phase: A: acetonitrile, B: water; 0-20 min: 20-40% A, 20-26min: 40-20% A
- Detector wavelength: 203nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
notoginsenoside R1	2.528	8.819	36.89	267.2	39839	0.91
ginsenoside Rg1	2.977	9.944	231.45	1604.7	50644	1.05
ginsenoside Rb1	6.126	17.815	116.93	913.5	127711	0.93

# Naolejing Syrup (*Naolejing*) – 脑乐静

## Sample source

Commercially available Naolejing Syrup

## Chemical reference substances

Ammonium glycyrrhizinate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0731-9704)

## Preparation of test solution

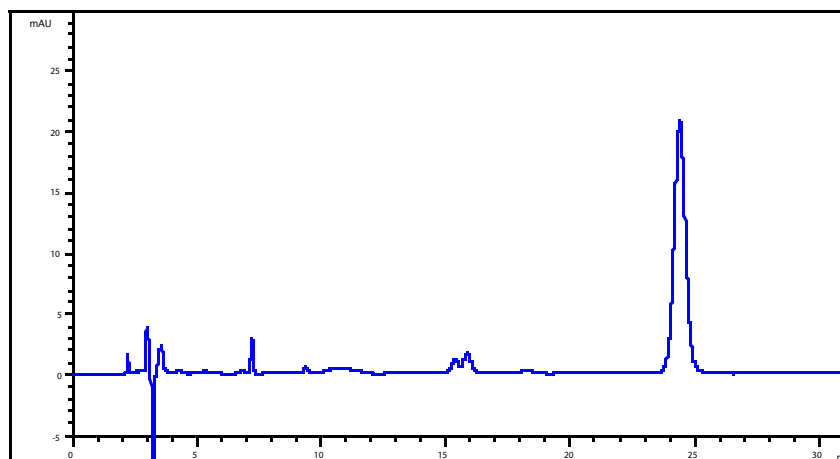
Accurately measure 10 ml of the syrup in a 50 mL volumetric flask, dilute to volume with dilute ethanol TS, shake well, and filter. Discard the initial filtrate, accurately measure 1 mL of the filtrate, in a 10 mL volumetric flask, dilute to volume with dilute ethanol TS, shake well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: Agilent TC-C18 4.6×250, 5  $\mu$ m (518925-902)
- Column temperature: 20 °C
- Mobile phase: methanol-2.5% glacial acetic acid (35:65)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu$ L

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Area (mAU*s)	n	USP T <sub>r</sub>
Glycyrrhizinic acid	8.76	24.41	662.0	14299	1.03

# Bovine Bezoar (*Calculus Bovis*) – 八珍益母丸

## Sample source

Commercially available Japanese  
Ardisia Herbs

## Chemical reference substances

Bilirubin (National Institute for the  
Control of Pharmaceutical and Bi-  
ological Products, Batch number:  
100077-200402)

## Preparation of test solution

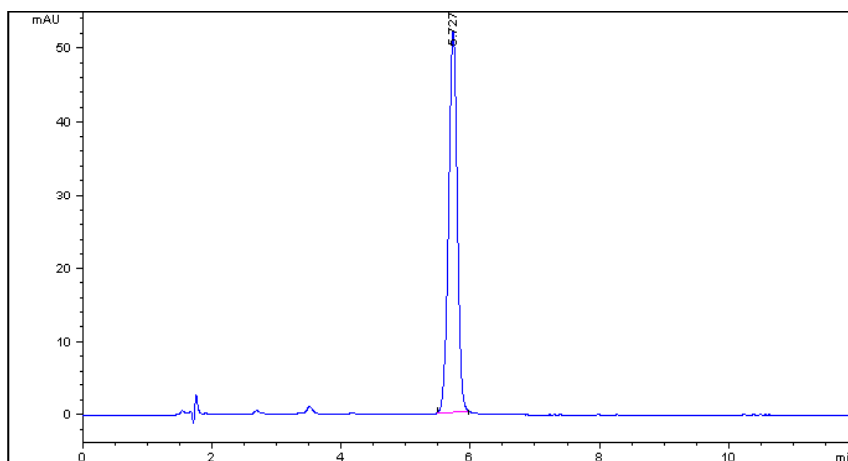
Accurately weigh 5 mg of the  
powder in a 25 mL amber volumet-  
ric flask. Add 20 mL of a mixture  
of chloroform and glacial acetic  
acid (4:1), treat ultrasonically for  
10 minutes, dilute with the mixture  
to volume and mix well. Filter  
through a millipore membrane  
(0.45 µm) and use the filtrate as  
the test solution. Stored in a dark  
place and protect from light.

## Chromatographic conditions

- Column: ZORBAX SB C18  
4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-ace-  
tonitrile-2% glacial acetic acid  
(72:25:3)
- Detector wavelength: 452 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary  
pump with vacuum degasser
- Agilent 1200 Series high-perfor-  
mance autosampler
- Agilent 1200 Series thermosta-  
ted column compartment
- Agilent 1200 Series variable  
wavelength detector
- System control through Agilent  
ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Bilirubin	3.773	5.727	51.99	488.8	8765	0.97

# Niuhuang Jiangya Capsules (*Niuhuang Jiangya Jiaonang*)

## 牛黄降压胶囊

### Sample source

Commercially available Niuhuang Jiangya Capsules

### Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

### Preparation of test solution

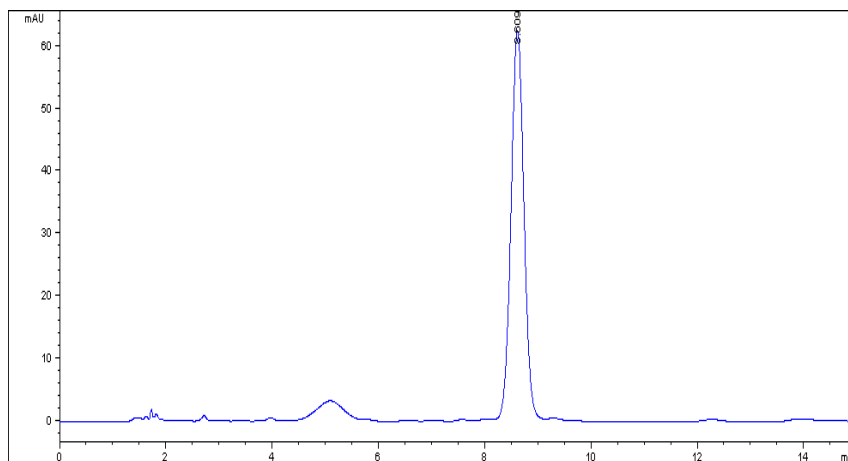
Grind the contents of the capsules to a fine powder. Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of dilute ethanol TS, stopper tightly and weigh. Heat under reflux for 30 minutes, allow to cool, weigh again, replenish the lost weight with dilute ethanol TS, stir well and filter. Accurately transfer 5 mL of the solution to a 100 mL volumetric flask and add dilute ethanol TS to volume, mix well and filter, use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid (50:50:1)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	2.444	8.609	62.06	1039.5	6206	1.03

# Niuhuang Jiangya Capsules (*Niuhuang Jiangya Jiaonang*)

## 牛黄降压胶囊

### Sample source

Commercially available Niuhuang Jiangya Capsules

### Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

### Preparation of test solution

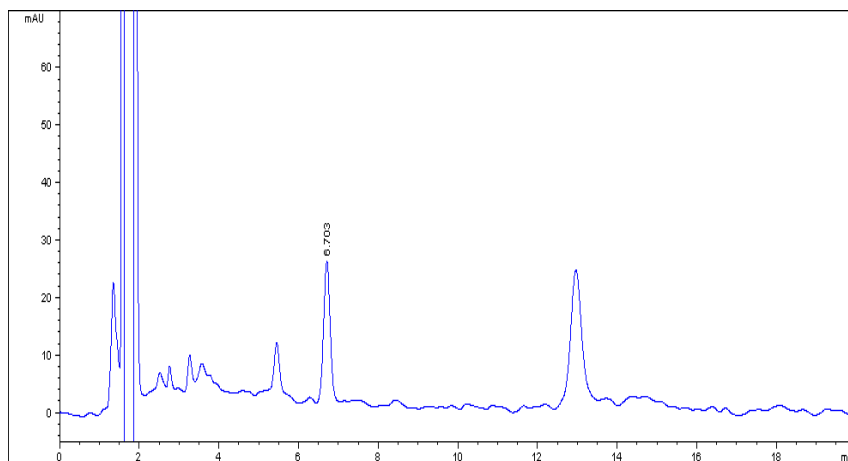
Grind the contents of the capsules to a fine powder. Accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 50 mL of water, stopper tightly and weigh. Treat ultrasonically for 45 minutes, allow to cool, weigh again, replenish the lost weight with water, stir well and centrifuge. Apply 10 mL of the supernatant to a column (1.5 cm in inner diameter), packed with 3 g of dry polyamide and elute with water, collect 60 mL of the eluents. Evaporate to dryness on a water bath, dissolve the residue in dilute ethanol TS, transfer to a 10 mL volumetric flask and add dilute ethanol TS to volume, mix well and filter, use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (15:85)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	3.469	6.703	24.56	279.2	8154	1.04

# Niuhuang Jiangya Pills (*Niuhuang Jiangya Wan*) – 牛黄降压丸

## Sample source

Commercially available Niuhuang Jiangya Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

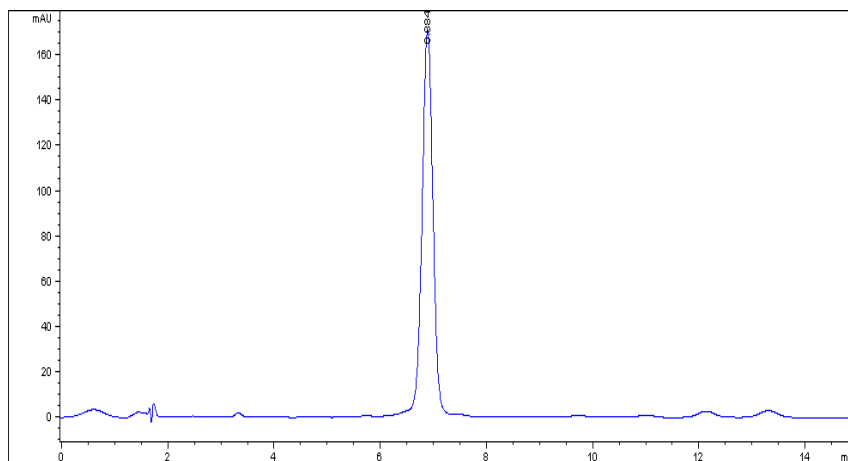
Grind the pills to a fine powder. Accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 50 mL of dilute ethanol TS, stopper tightly and weigh. Heat under reflux for 30 minutes, allow to cool, weigh again, replenish the lost weight with dilute ethanol TS, stir well and filter. Accurately transfer 5 mL of the solution to a 100 mL volumetric flask and add dilute ethanol TS to volume, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid (46:54:1)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicarin		6.884	168.55	2350.8	5769	0.99

# Niuhuang Jiangya Pills (*Niuhuang Jiangya Wan*) – 牛黄降压丸

## Sample source

Commercially available Niuhuang Jiangya Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

## Preparation of test solution

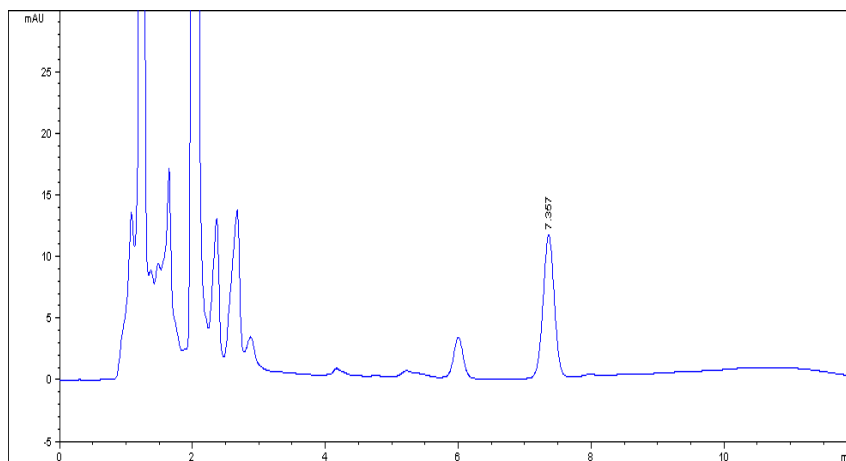
Grind a quantity of the pills to a fine powder. Accurately weigh 2 g of the powder in a stoppered conical flask, accurately add 50 mL of water, stopper tightly and weigh, treat ultrasonically for 45 minutes, allow to cool, weigh again, replenish the lost weight with water, mix well and centrifuge. Accurately apply 10 mL of the supernatant to a column (1.5 cm in inner diameter), packed with 3 g of dry polyamide, using water as the eluent. Collect 60 mL of the eluent, evaporate to dryness on a water bath, dissolve the residue in dilute ethanol TS, transfer to a 10 mL volumetric flask, dilute to volume, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (15:85)
- Detector wavelength: 230 nm
- Flow rate: 1.0 ml/min
- Injection volume: 5 µl

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	3.905	7.357	11.59	135.7	9300	1.01



# Niuhuang Jiedu Tablets (*Niuhuang Jiedu Pian*) – 牛黄解毒片

## Sample source

Commercially available Niuhuang Jiedu Tablets

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

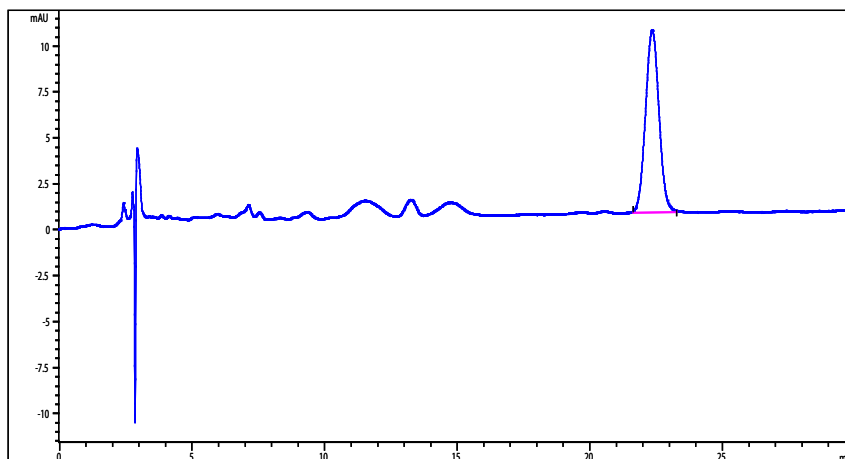
Remove the coatings from 20 tablets and grind to a fine powder. Accurately weigh 0.3 g of the powder, add 30 ml of 70% ethanol, treat ultrasonically for 20 minutes, allow to cool and filter. Transfer the filtrate to a 50 mL volumetric flask, wash the container and residue with small quantity of 70 % ethanol in portions, combine the washings in the same volumetric flask, dilute to volume with 70 % ethanol and shake well. Accurately measure 2 mL of the solution in a 10 mL volumetric flask, dilute to volume with 70 % ethanol and shake well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-0.3 % phosphoric acid (42:58)
- Detector wavelength: 315 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicarin	7.942	22.354	9.93	350.1	9494	1.04

# Niuhuang Jiedu Pills (*Niuhuang Jiedu Wan*) – 牛黄解毒丸

## Sample source

Commercially available Niuhuang Jiedu Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

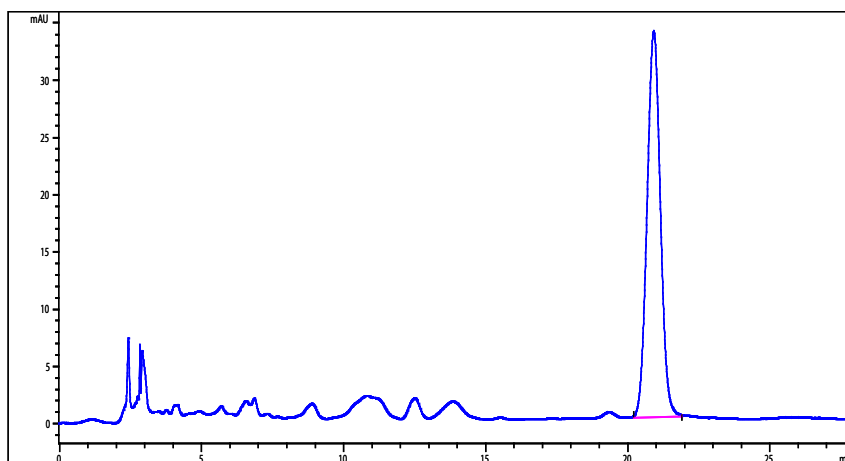
Remove the coatings from 20 tablets and grind to a fine powder. Accurately weigh 0.3 g of the powder, add 30 ml of 70% ethanol, treat ultrasonically for 20 minutes, allow to cool and filter. Transfer the filtrate to a 50 mL volumetric flask, wash the container and residue with small quantity of 70 % ethanol in portions, combine the washings in the same volumetric flask, dilute to volume with 70 % ethanol and shake well. Accurately measure 2 mL of the solution in a 10 mL volumetric flask, dilute to volume with 70 % ethanol and shake well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-0.36% phosphoric acid (42:58)
- Detector wavelength: 315 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	7.367	20.917	33.70	1102.1	9568	1.04

# Niuhuang Qianjin Powder (*Niuhuang Qianjin San*) – 牛黄千金散

## Sample source

Commercially available Niuhuang Qianjin Powder

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

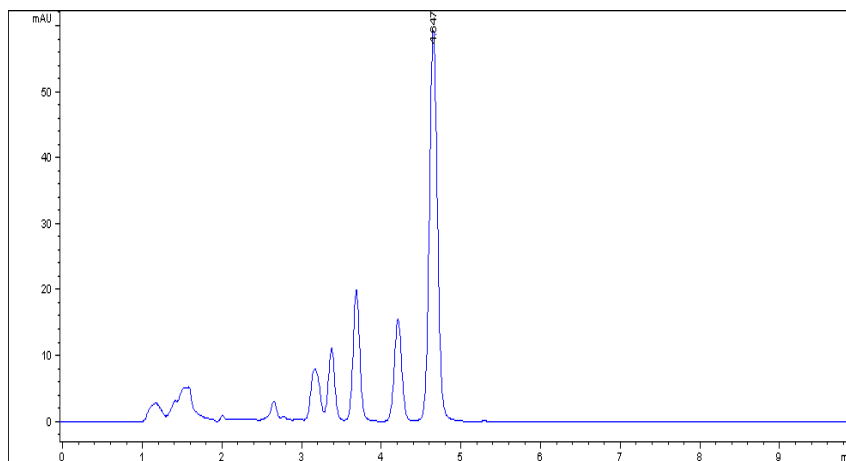
Accurately weigh about 0.5 g of the powder in a stoppered conical flask, mix well, accurately add 50 mL of a mixture of hydrochloric acid and methanol (1:100), weigh. Heat under reflux on a water bath at 60 °C for 15 minutes. Treat ultrasonically for 30 minutes, allow to cool, weigh again, and replenish the lost weight with a mixture of hydrochloric acid and methanol (1:100). Shake well, filter. Accurately transfer 2 mL of the filtrate to a 10 mL volumetric flask, dilute with methanol to volume, shake well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (containing 0.34% potassium dihydrogen phosphate and 0.17% sodium dodecylsulphonate) (50:50)
- Detector wavelength: 346nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	2.098	4.647	59.19	412.3	10783	1.05

# Niuhuang Shangqing Pills (*Niuhuang Shangqing Wan*)

牛黄上清丸

## Sample source

Commercially available Niuhuang Shangqing Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

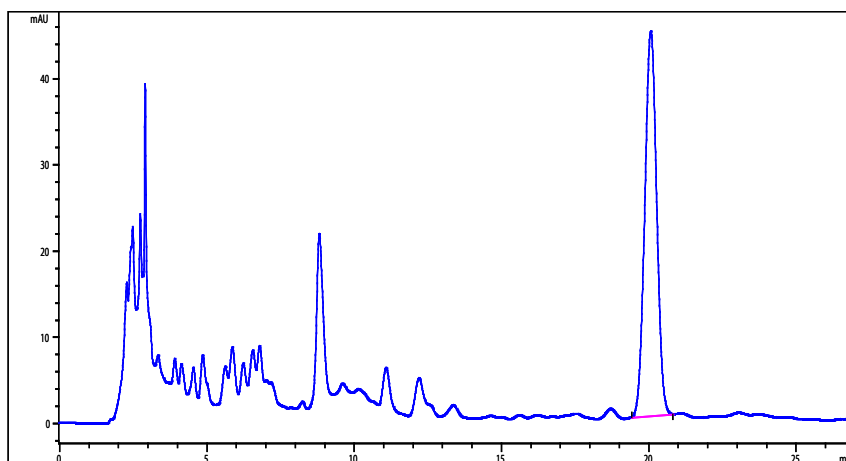
Cut a quantity of the pills into pieces, accurately weigh 2 g of the powder, accurately add 50 mL of dilute ethanol TS and weigh, treat ultrasonically for 3 hours, allow to cool, weigh again, replenish the lost weight with dilute ethanol TS. Allow to stand and use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-0.36% phosphoric acid (42:58)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	7.027	20.067	44.65	1256.7	11700	1.02

# Niuhuang Xiaoyan Tablets (*Niuhuang Xiaoyan Pian*) – 牛黄消炎片

## Sample source

Commercially available Niuhuang Xiaoyan Tablets

## Chemical reference substances

1. Cinobufagin, 2. Bufogenin  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1.803-200203, 2.718-200207)

## Preparation of test solution

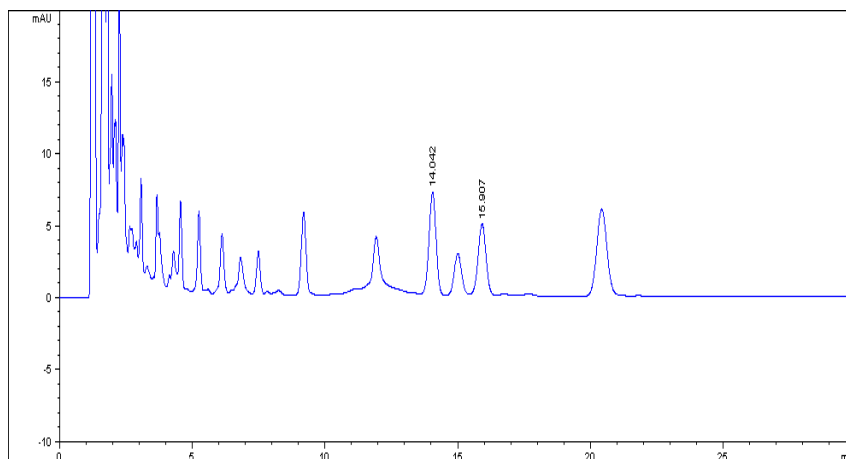
Accurately weigh 20 tablets, remove the coatings and grind to a fine powder. Accurately weigh 0.6 g of the powder in a stopper conical flask, accurately add 25 mL of methanol, stopper tightly, weigh, shake well, allow to stand overnight, treat ultrasonically for 20 minutes, cool, weigh again, replenish the lost weight with methanol, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-0.5% potassium dihydrogen phosphate (adjust pH to 3.2 with phosphoric acid) (40:60)
- Detector wavelength: 296nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Cinobufagin		14.042	7.14	131.0	13607	0.98
Bufogenin		15.907	4.98	102.7	13690	0.99

# Qiju Dihuang Pills (*Qiju Dihuang Wan*) – 杞菊地黄丸

## Sample source

Commercially available Qiju Dihuang Pills

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110708-200205)

## Preparation of test solution

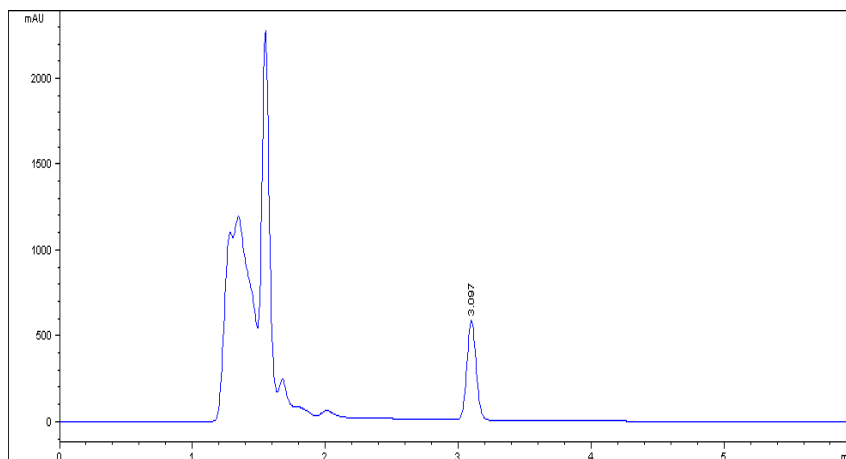
Grind the pills into pieces, accurately weigh 0.5 g in a stopper conical flask, accurately add 50 mL of 70 % methanol, stopper tightly and weigh. Treat ultrasonically for 45 minutes, allow to cool, weigh again, replenish the lost weight with 70 % methanol, and shake well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (70:30)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	1.065	3.097	580.25	2818.4	9512	1.05

# Qiju Dihuang Pills (*Qiju Dihuang Wan*) – 杞菊地黄丸

## Sample source

Commercially available Qiju Dihuang Pills

## Chemical reference substances

Loganin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111640-200401)

## Preparation of test solution

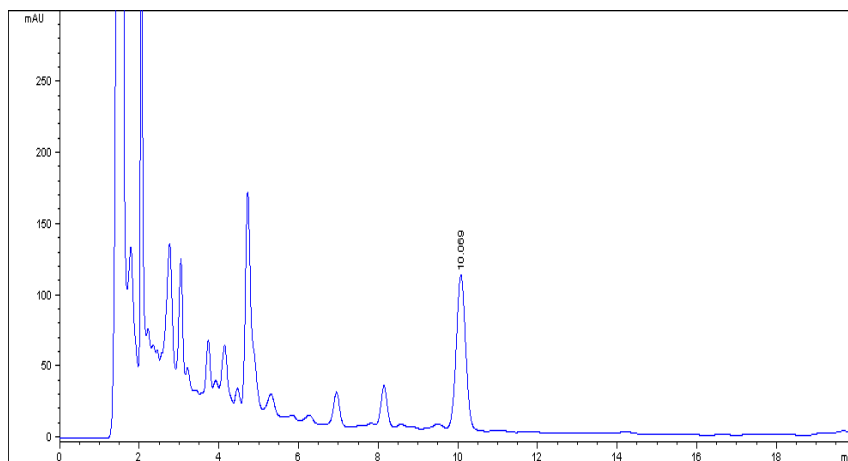
Grind the pills to a fine powder, accurately weigh 1 g in a stoppered conical flask, accurately add 25 mL of 50 % methanol, stopper tightly and weigh. Heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with 50 % methanol, shake well and filter. Accurately apply 10 mL of the filtrate to a neutral alumina column (100-200 mesh, 4 g, 1 cm in inner diameter), elute with 50 mL of 40 % methanol, collect the eluent, and evaporate to dryness. Dissolve the residue in 50 % methanol and accurately transfer to a 5 mL volumetric flask, dilute with 50 % methanol to volume, and shake well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-methanol-0.1% phosphoric acid (10:5:85)
- Detector wavelength: 236 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Loganin	7.391	10.069	108.23	1756.3	8991	1.01

# Qipi Pills (*Qipi Wan*) – 启脾丸

## Sample source

Commercially available Qipi Pills

## Chemical reference substances

Ammonium glycyrrhizinate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0731-9704)

## Preparation of test solution

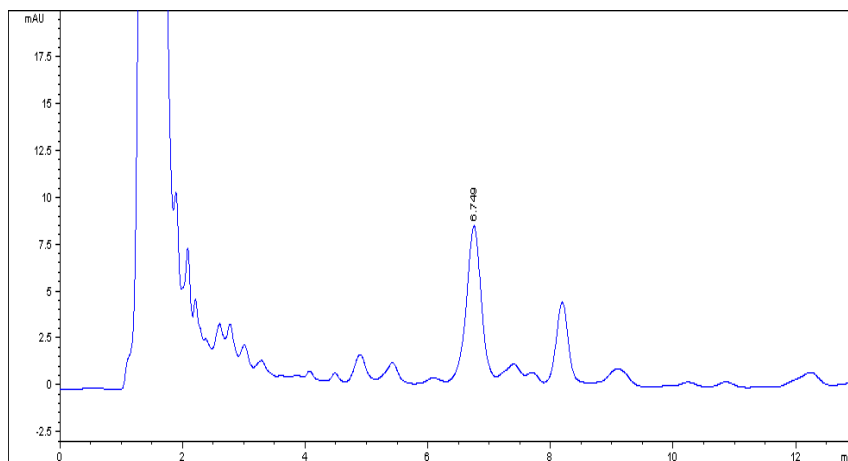
Cut the pills into pieces, mix well, accurately measure 0.2 g in a stoppered conical flask, accurately add 10 mL of the mobile phase, and weigh. Allow to stand overnight, treat ultrasonically for 30 minutes, allow to cool, weigh again, and replenish the lost weight with mobile phase. Mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-0.2mol/L ammonium acetate- glacial acetic acid (62:38:1)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Glycyrrhizinic acid	4.624	6.749	8.27	137.8	4188	0.97



# Qizhi Weitong Granules (*Qizhi Weitong Keli*) – 气滞胃痛颗粒

## Sample source

Commercially available Qizhi Weitong Keli

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0736-200220)

## Preparation of test solution

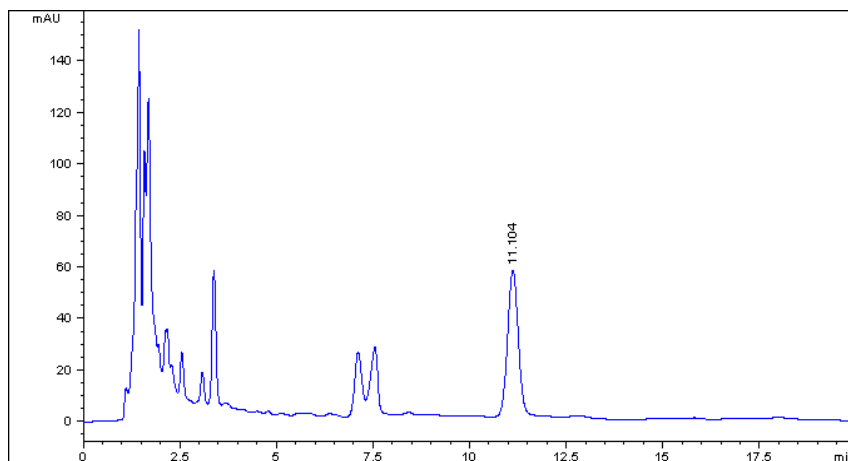
Grind the granules to a fine powder, accurately weigh 2 g in a stoppered conical flask. Accurately add 50 mL of water, stopper tightly and weigh. Treat ultrasonically for 60 minutes, allow to cool, weigh again, replenish the lost weight with water, shake well and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.02mol/L potassium dihydrogen phosphate (26:74)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	8.253	11.104	56.74	1088.3	7923	1.04

# Qiangjin Zhidai Pills (*Qiangjin Zhidai Wan (Shuiwan)*)

## 千金止帶丸（水丸）

### Sample source

Commercially available Qiangjin Zhidai Pills (Watered Pills)

### Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110736-200220)

### Preparation of test solution

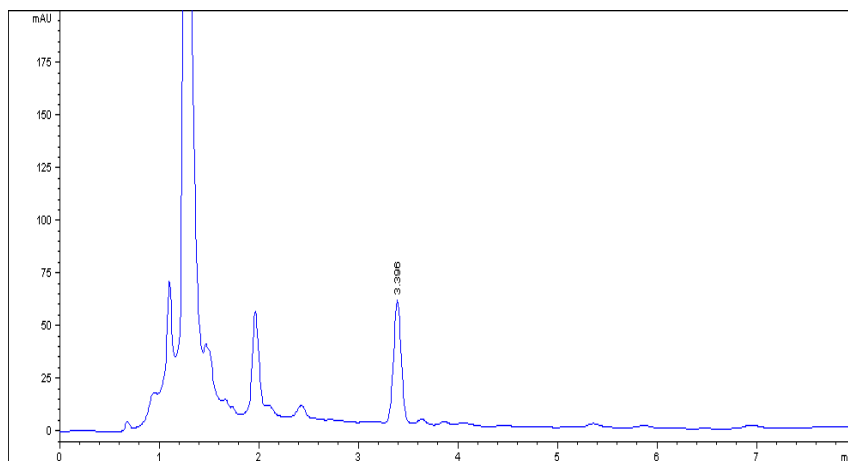
Grind the pills to a fine powder, accurately weigh about 1 g in a stoppered conical flask, accurately add 25 mL of 30 % ethanol solution, stopper and accurately weigh. Treat ultrasonically for 30 minutes, cool, accurately weigh again, and replenish the lost weight with 30 % solution of methanol. Mix well, filter with a millipore membrane (0.45  $\mu$ m) and use successive filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu$ m (883975-902)
- Column temperature: 40  $^{\circ}$ C
- Mobile phase: methanol-water (12:88)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu$ L

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	1.264	3.396	58.51	313.8	9453	1.02

# Pharbitis Seed (*Semen Pharbitidis*) – 牽牛子

## Sample source

Commercially available Pharbitis Seed

## Chemical reference substances

1. Caffeic acid, 2. Caffeic acid acetate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110885-200102, 2. 111678-200401)

## Preparation of test solution

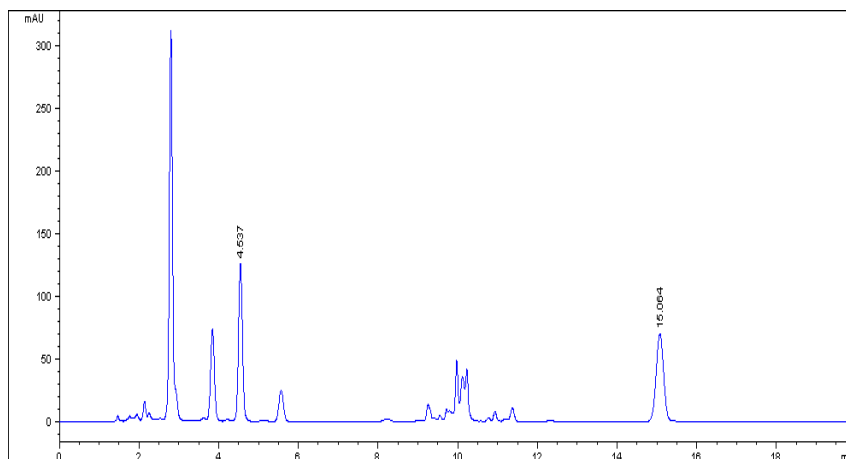
Accurately weight 2 g of the powder in a Soxhlet extractor, extract with a quantity of petroleum ether (60-90 °C) under reflux for 2 hours, discard petroleum ether, and evaporate the residue to dryness. Extract the residue with a mixture of chloroform and methanol (3:1) for 6 hours, evaporate the extract to a small quantity, transfer to a 10 mL volumetric flask, wash the container with the same solvent, combine the washings in the same volumetric flask. Dilute to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: A: acetonitrile, B: 0.04 % phosphoric acid (containing 2 % isopropanol); 0-6min, A: 15 %; 6-7min, A: 15-28 %; 7-20 min, A: 28 %
- Detector wavelength: 325 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Caffeic acid	2.025	4.537	126.1	870.6	10475	1.04
Caffeic acid acetate	9.043	15.064	70.07	902.6	31751	0.99

# Qinlian Tablets (*Qinlian Pian*) – 芩连片

## Sample source

Commercially available Qinlian Tablets

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

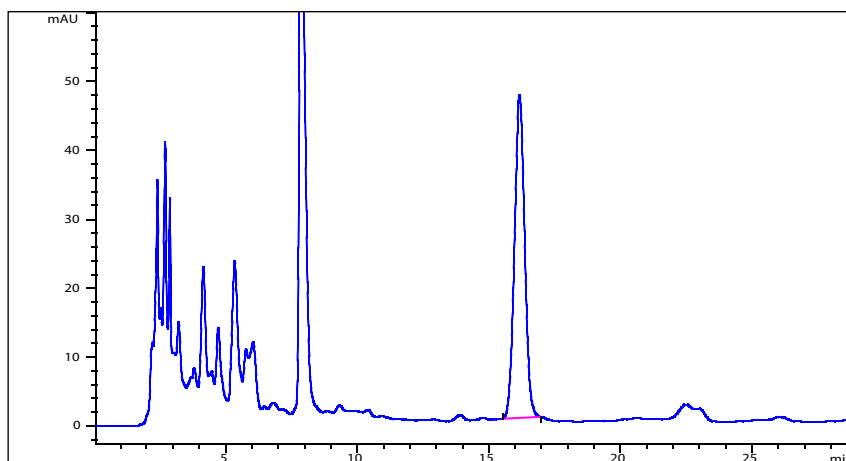
Grind the tablets to a fine powder, and accurately weigh 0.15 g in a 25 mL volumetric flask. Add 20 mL of 70 % ethanol, treat ultrasonically for 20 minutes, allow to cool, dilute to volume with 70 % ethanol, and mix well. Allow to stand, filter the supernatant through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 40  $^{\circ}\text{C}$
- Mobile phase: methanol-4% glacial acetic acid (37:63)
- Detector wavelength: 277nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	5.468	16.171	46.86	1268.3	8344	1.03

# Ash Bark (*Cortex Fraxini*) – 秦皮

## Sample source

Commercially available Ash Bark

## Chemical reference substances

1. Aesculin, 2. Aesculetin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110740-200104, 2. 110741-200105)

## Preparation of test solution

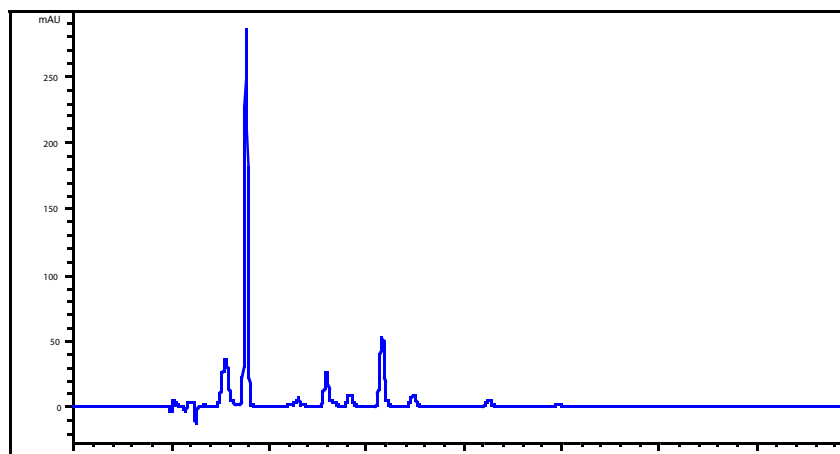
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol, weigh, heat under reflux on a water bath for 60 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Eclipse Plus C18, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (959990-902)
- Column temperature: 40  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.1% phosphoric acid (14:86)
- Detector wavelength: 334 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP $T_r$
aesculin	4.419	283.71	1595.6	14779	1.03
aesculetin	7.893	53.35	456.1	19906	1.08

# Qingfei Yihuo Pills (*Qingfei Yihuo Wan*) – 清肺抑火丸

## Sample source

Commercially available Qingfei Yihuo Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

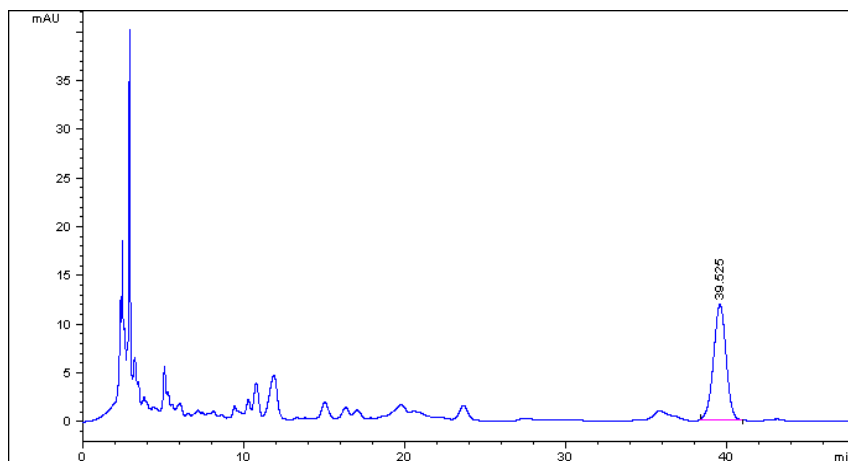
Grind the pills to a fine powder, accurately weigh 0.25 g, accurately add 50 mL of 70 % ethanol and weigh. Heat under reflux for 3 hours, cool, and weigh again. Replenish the lost weight with 70 % ethanol, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 μm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-phosphoric acid (38:62:0.3)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	14.81	39.525	11.91	650.4	12420	0.96

# Orientvine Stem (*Caulis Sinomenii*) – 青风藤

## Sample source

Commercially available Orientvine Stem

## Chemical reference substances

Sinomenine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110774-200206)

## Preparation of test solution

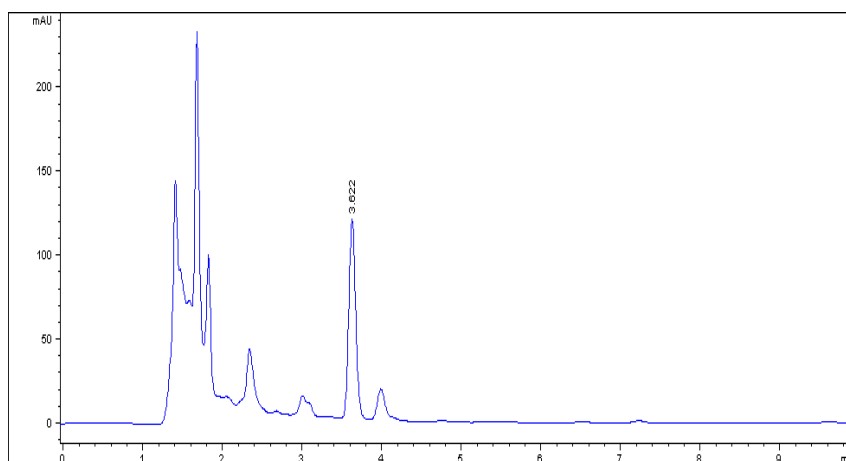
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 20 mL of 70 % ethanol, stopper tightly, weigh, treat ultrasonically for 20 minutes, allow to cool, weigh again and replenish the lost weight with 70 % ethanol, shake thoroughly, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 35 °C
- Mobile phase: methanol-phosphate BS (to 0.01 mol/L sodium hydrogen phosphate solution, monitor the pH value to 8.0 with 0.01 mol/L sodium dihydrogen phosphate solution, and monitor the pH value to 9.5 with 1 % triethylamine) (58:42)
- Detector wavelength: 262 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Sinomenine	1.173	3.622	118.58	707.6	8756	1.07

# Qingguo Pills (*Qingguo Wan*) – 青果丸

## Sample source

Commercially available Qingguo Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

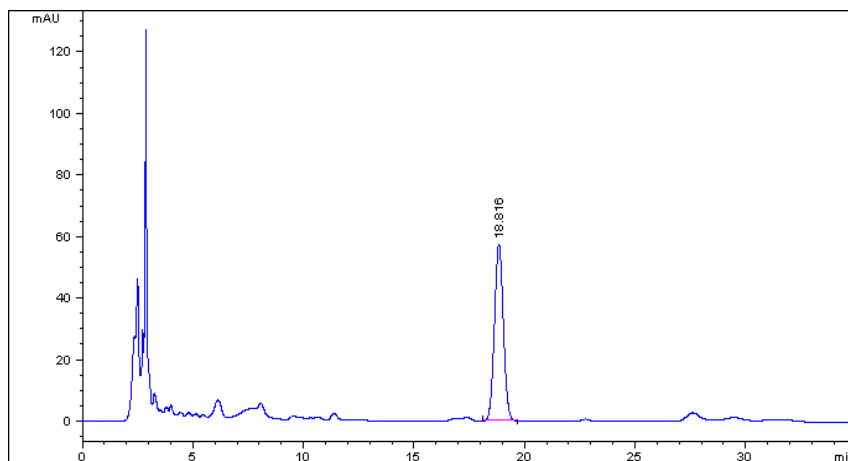
Cut a quantity of the pills into pieces, accurately weigh 1 g and grind well with 0.5 g of kieselguhr. Add 40 mL of 70 % ethanol, heat under reflux for 2 hours, cool, and filter. Wash the container and residue with a quantity of 70 % ethanol. Combine the washings and the filtrate in a 100 mL volumetric flask, dilute to volume with 70 % ethanol, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.36% phosphoric acid (43:57)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	6.527	18.816	57.55	1614.0	10753	1.04



# Qinghou Liyan Granules (*Qinghou Liyan Keli*) – 清喉利咽颗粒

## Sample source

Commercially available Qinghou Liyan Granules

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

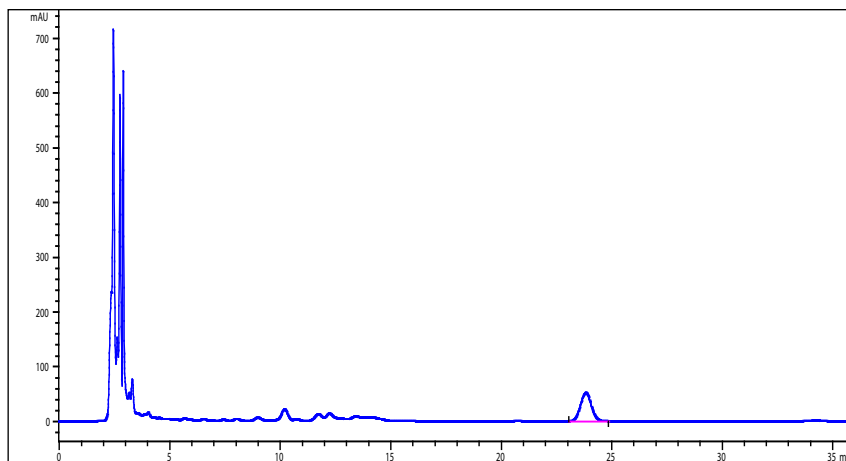
Grind the granules to a fine powder, accurately weigh 0.5 g in a 50 mL stoppered conical flask, accurately add 20 mL of water, weigh, treat ultrasonically for 2 hours, allow to cool, weigh again, replenish the lost weight with water, mix well. Accurately add 20 mL of ethanol, mix well, allow to stand overnight and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 μm (880975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-3.0% glacial acetic acid (43:57)
- Detector wavelength: 283nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	8.535	23.827	52.24	1826.6	11057	1.03

# Qinghouyan Mixture (*Qinghouyan Heji*) – 清喉咽合剂

## Sample source

Commercially available Qinghouyan Mixture

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

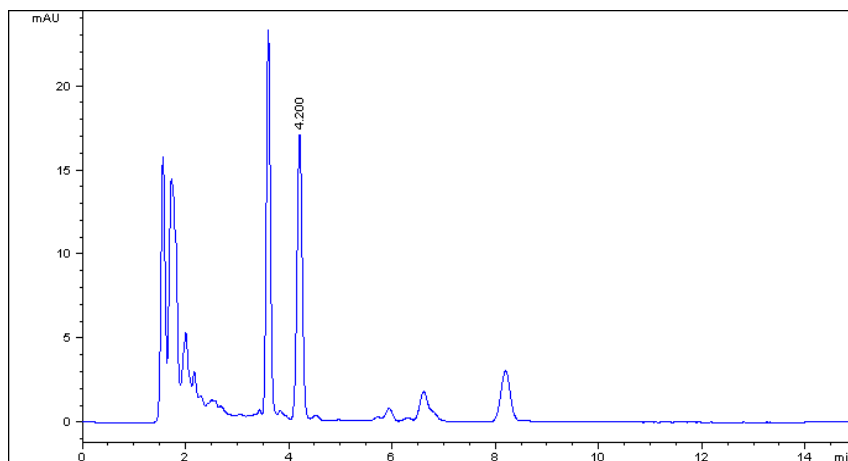
Accurately measure 1 mL of the mixture in a 50 mL volumetric flask, add a quantity of methanol, treat ultrasonically for 20 minutes, allow to cool, dilute to volume with methanol and shake well. Accurately measure 10 mL in a 25 mL volumetric flask, dilute to volume with methanol and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.2% phosphoric acid (25:75)
- Detector wavelength: 278 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	1.800	4.20	17.03	121.4	8194	1.02

# Qinglin Granules (*Qinglin Keli*) – 清淋颗粒

## Sample source

Commercially available Qinglin Granules

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110749-200309)

## Preparation of test solution

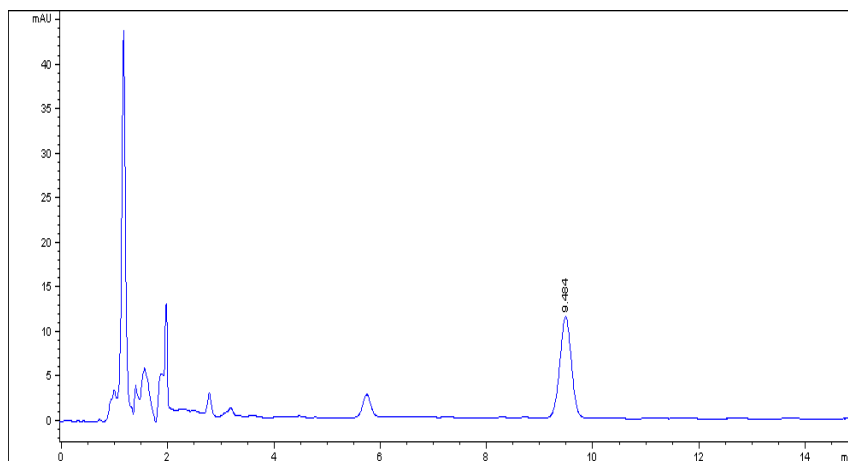
Grind a quantity of the granules to a fine powder, accurately weigh 0.25 g in a stoppered conical flask. Accurately add 25 mL of methanol, stopper tightly, weigh and treat ultrasonically for 20 minutes. Allow to reach room temperature, weigh again and replenish the lost weight with methanol. Mix thoroughly, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (11:89)
- Detector wavelength: 238 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide	6.903	9.484	11.33	169.6	9329	1.00

# Qingning Pills (*Qingning Wan*) – 清宁丸

## Sample source

Commercially available Qingning Pills

## Chemical reference substances

1. Emodin, 2. Chrysophanol  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110756-200210, 2. 110796-200309)

## Preparation of test solution

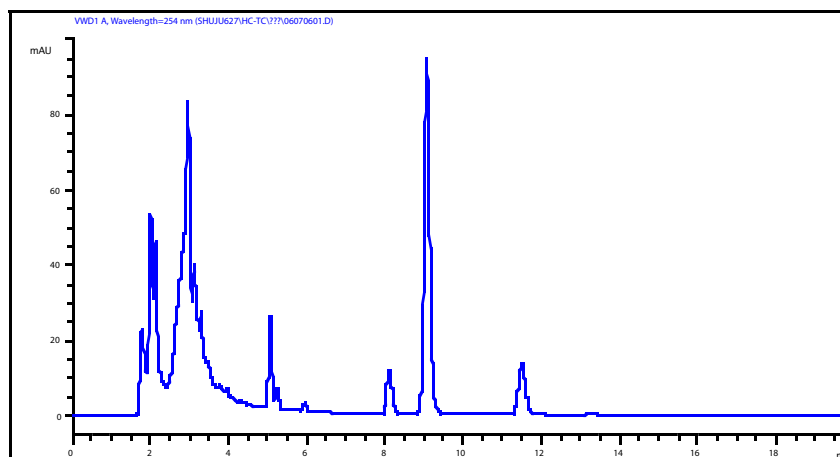
Grind a quantity of the pills to a fine powder, accurately weigh 0.1 g in a conical flask, accurately add 25 mL of a mixture of hydrochloric acid and methanol (1:25) and weigh. Heat under reflux on a water bath for 2 hours, allow to cool, and replenish the lost weight with a mixture of hydrochloric acid and methanol (1:25). Mix well and filter. Accurately measure 5 mL of the filtrate in an evaporating dish, evaporate to dryness. Dissolve the residue in a quantity of methanol, transfer to a 5 mL volumetric flask, dilute to volume with methanol, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (518925-902)
- Column temperature: 30  $^{\circ}\text{C}$
- Mobile phase: methanol-0.1% phosphoric acid (85:15)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP $T_r$
Emodin	8.112	11.70	108.9	17987	1.07
Chrysophanol	9.077	94.19	945.1	20163	1.08

# Qingwen Jiedu Pills (*Qingwen Jiedu Wan*) – 清瘟解毒丸

## Sample source

Commercially available Qingwen Jiedu Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

## Preparation of test solution

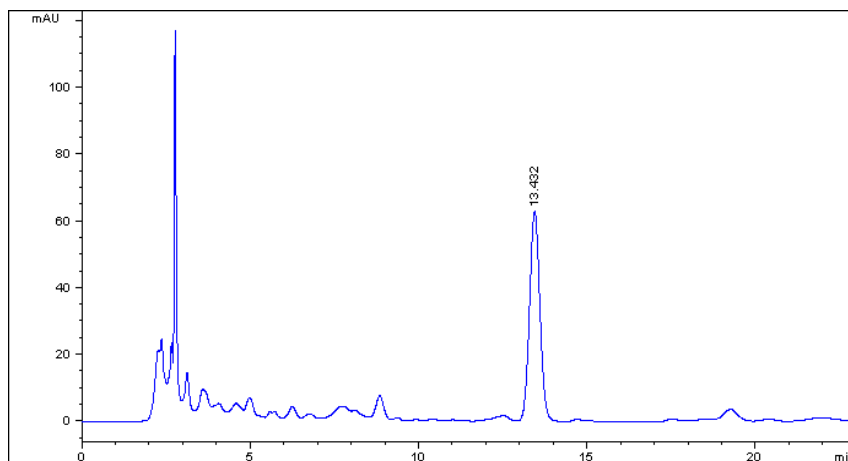
Cut a quantity of the pills into pieces, mix well, accurately weigh 1 g, grind with 0.5 g of kieselguhr, transfer to a stoppered conical flask, accurately add 50 mL of 70 % ethanol, stopper tightly, and weigh. Treat ultrasonically for 30 minutes, cool, weigh again, replenish the lost weight with 70 % ethanol, and shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and used the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-water-phosphoric acid (47:53:0.2)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	4.373	13.432	62.68	1334.0	9313	1.05

# Qingxuan Pills (*Qingxuan Wan*) – 清眩丸

## Sample source

Commercially available Qingxuan Pills

## Chemical reference substances

Imperatorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110826-200307)

## Preparation of test solution

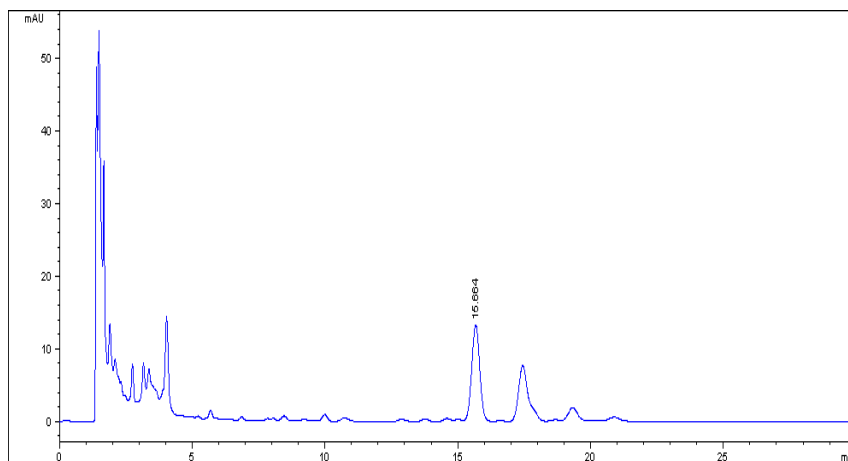
Cut a quantity of pills into pieces, accurately weigh about 1 g in a stoppered conical flask. Accurately add 25 mL of methanol, stopper tightly and weigh, treat ultrasonically for 45 minutes. Allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 40 °C
- Mobile phase: methanol-water (55:45)
- Detector wavelength: 248nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Imperatorin	9.442	15.664	13.29	279.4	12855	1.00

# Mile Swertia Tablets (*Tabellae Swertiae Mileensis*) – 青叶胆片

## Sample source

Commercially available Mile Swertia Tablets

## Chemical reference substances

Swertiamain (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0785-200203)

## Preparation of test solution

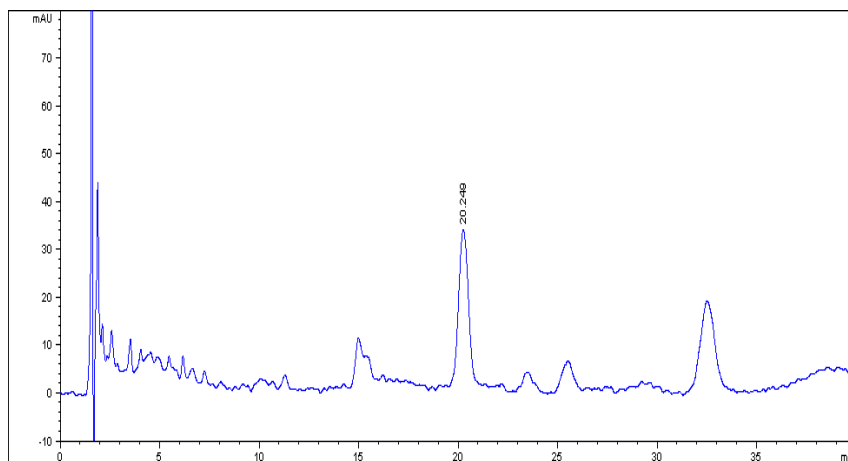
Remove the coatings of 30 tablets, grind to a fine powder, accurately weigh about 12 powdered tablets in a 100 mL volumetric flask, add 80 mL of methanol, allow to soak for 20 minutes, treat ultrasonically for 15 minutes, allow to cool, add methanol to volume, mix well and filter. Discard the initial filtrate, and use the successive filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-0.3% formic acid (14:86)
- Detector wavelength: 237 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Swertiamain	12.499	20.249	32.66	1115.1	8189	1.02

# Qingyin Pills (*Qingyin Wan*) – 清音丸

## Sample source

Commercially available Qingyin Pills

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110752-200209)

## Preparation of test solution

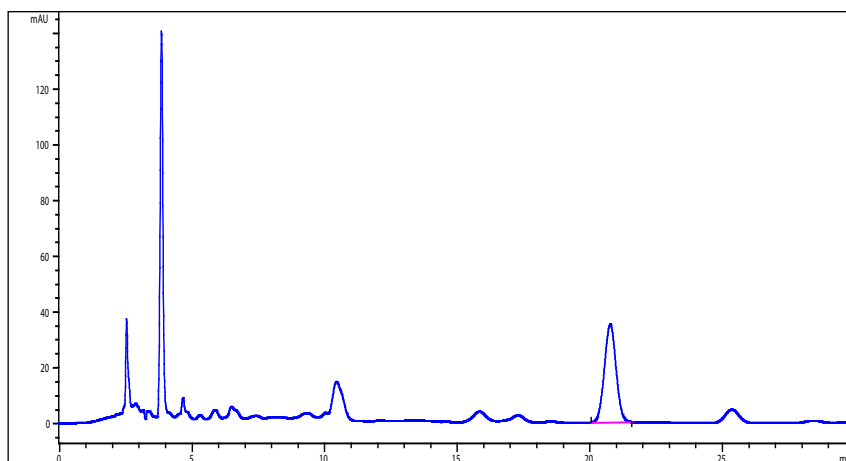
Cut the pills into pieces, accurately weigh 1 g, grind with 0.5 g of kieselguhr, accurately add 10 mL of acetyl acetate, stopper tightly, and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with acetyl acetate, shake well, centrifuge, filter the supernatant, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.5% acetic acid (22:78)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	7.307	20.768	35.20	1078.0	10665	1.02



# Reyanning Granules (*Reyanning Keli*) – 热炎宁颗粒

## Sample source

Commercially available Reyanning Granules

## Chemical reference substances

Emodin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110756-200210)

## Preparation of test solution

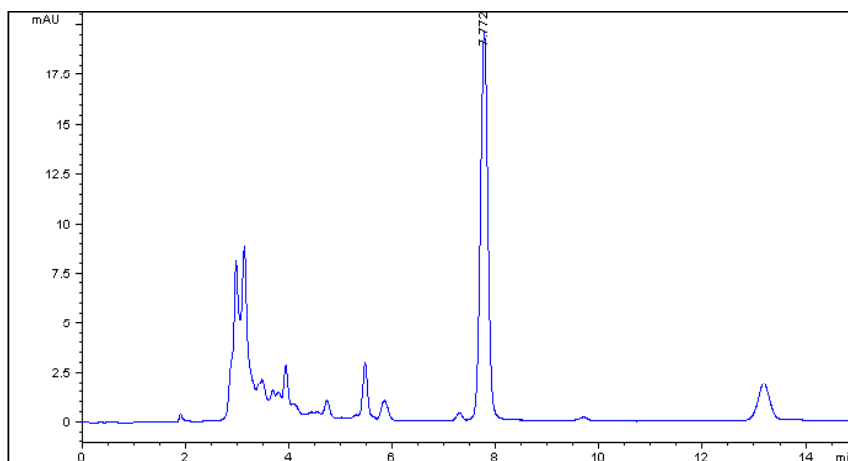
Grind the contents to a fine powder. Accurately weigh 2 g of the powder in a 50 mL stoppered conical flask, accurately add 25 mL of methanol, weigh. Treat ultrasonically for 30 minutes, allow to cool, and weigh again. Replenish the lost weight with methanol, mix well, and filter. Accurately measure 10 mL of the filtrate in a 50 mL round-bottom flask, evaporate the methanol in vacuum, add 10 mL of 2.5 mol/L solution of sulfuric acid, and treat ultrasonically for 5 minutes. Add 10 mL of chloroform, heat under reflux for 1 hour, cool, transfer to a separating funnel, wash the container with a quantity of chloroform, combine the washings in the same separating funnel, separate the chloroform layer, extract the water layer with two 10 mL quantities of chloroform, and combine the chloroform solutions. Dehydrate with a quantity of anhydrous sodium sulfate, wash the container and the filter paper with a quantity of chloroform, combine the washings with the chloroform extracts, and evaporate the chloroform in vacuum. Dissolve the residue in 10 mL of methanol, measured accurately, weigh, slightly heat in a water bath, allow to cool, and weigh again. Replenish the lost weight with methanol, mix well, and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: Hypersil ODS 4.6×250 mm, 5 μm (7991618-584)
- Column temperature: 26 °C
- Mobile phase: methanol-0.1% phosphoric acid (85:15)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	2.109	7.772	19.48	191.0	15105	1.02

# Renqing Mangjue Pills (*Renqing Mangjue*) – 仁青芒觉

## Sample source

Commercially available Renqing Mangjue Pills

## Chemical reference substances

Strychnine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110705-200205)

## Preparation of test solution

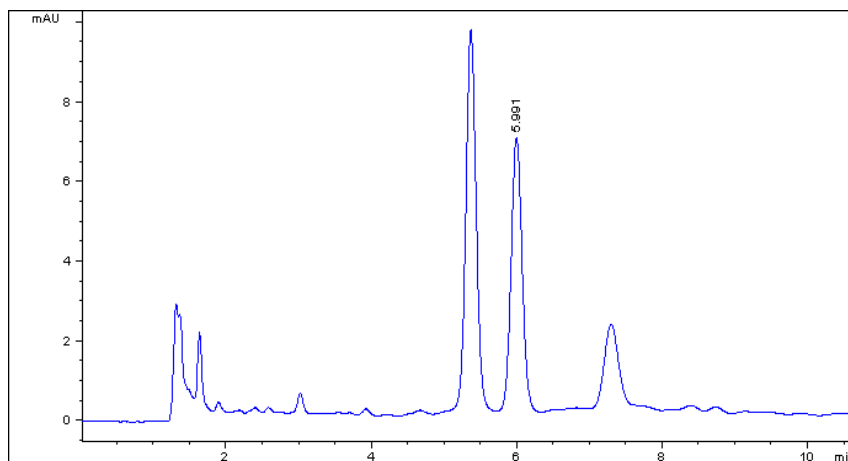
Accurately weigh 0.9 g of the powder in a stoppered conical flask, accurately add 50 mL of chloroform and 2 mL of concentrated ammonia TS, stopper tightly, and shake gently. Weigh, allow to stand for 24 hours, weigh again, replenish the lost weight with chloroform, mix well, and filter. Accurately measure 20 mL of the filtrate in a separating funnel, extract by shaking with five 20 mL quantities of sulfuric acid solution (3:100). Combine the extracts, adjust pH value to 9-10 with concentrated ammonia TS, extract with five 20 mL quantities of chloroform, combine the chloroform extracts, and evaporate to dryness in vacuum. Dissolve the residue in mobile phase, transfer to a 10 mL volumetric flask, dilute to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.01mol/L potassium dihydrogen phosphate (27:73) (pH 2.15)
- Detector wavelength: 254nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
	2.994	5.991	6.88	72.3	7752	1.05

# Ginseng (*Radix et Rhizoma Ginseng*) – 人參

## Sample source

Commercially available Ginseng

## Chemical reference substances

1. Ginsenoside Rb1, 2. Ginsenoside Rg1, 3. Ginsenoside Re (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 2. 110703-200322, 3. 0754-9912)

## Preparation of test solution

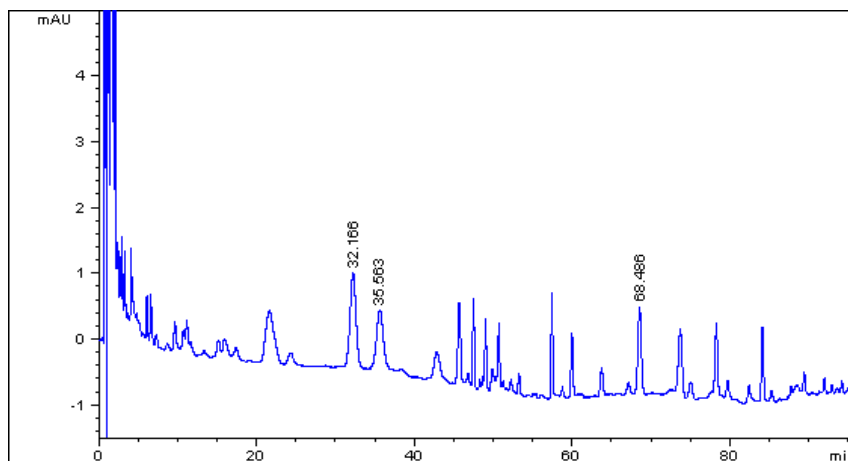
Accurately weigh 1 g of the powder in a Soxhlet extractor, add a quantity of chloroform, heat under reflux on a water bath for 3 hours, discard the chloroform solution, evaporate the solvent from the residue. Transfer the residue with the extractor to a 100 mL conical flask. Accurately add 50 mL n-butanol saturated with water, stopper tightly, allow to stand overnight, treat ultrasonically for 30 minutes and filter. Evaporate accurately 25 mL of the filtrate to dryness in an evaporating dish, dissolve the residue in methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: A: acetonitrile, B: water; 0-35 min, A: 19 %; 35-55 min, A: 19-29 %; 55-70 min, A: 29 %; 70-100 min, A: 29-40 %
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
ginsenoside Rg1	20.444	32.166	1.44	75.1	8831	0.98
ginsenoside Re	22.709	35.563	0.89	53.4	8327	1.00
ginsenoside Rb1	44.657	68.486	1.33	40.6	119699	0.97

# Renshen Jianpi Pills (*Renshen Jianpi Wan*) – 人參健脾丸

## Sample source

Commercially available Renshen Jianpi Pills

## Chemical reference substances

hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110721-200211)

## Preparation of test solution

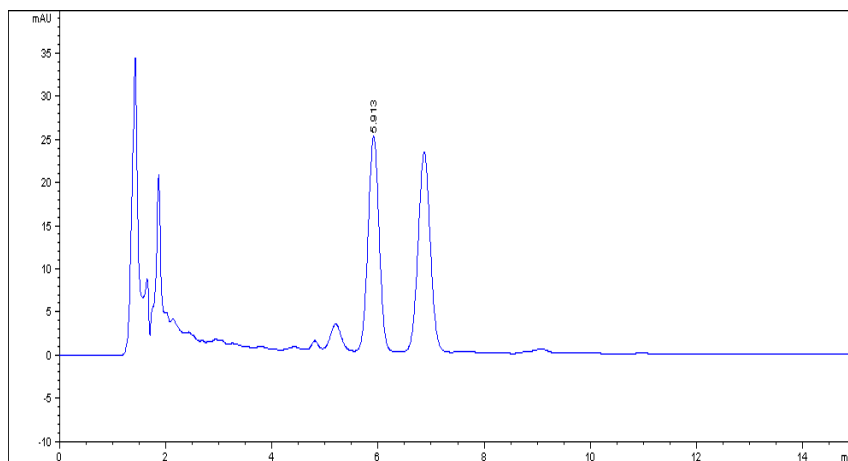
Cut a quantity of the pills into pieces, accurately weigh about 6 g, grind well with 6 g of kieselguhr to form a flake and cut into pieces. Transfer to a Soxhlet extractor, heat under reflux with 80 mL of petroleum ether (60-90 °C) for 3 hours. Discard the petroleum ether extract, evaporate the remaining solvent in the residue, add 80 mL of methanol, heat under reflux for 5 hours, allow to cool and filter. Transfer the filtrate to a 100 mL volumetric flask, wash the container with small quantities of methanol several times, filter the washings into the same flask, dilute with methanol to volume, and mix well as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-acetic acid (35:61:4)
- Detector wavelength: 284 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	3.927	5.913	24.79	357.6	3922	1.00

# Renshen Yangrong Pills (*Renshen Yangrong Wan*) – 人參養榮丸

## Sample source

Commercially available Renshen Yangrong Pills

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110721-200211)

## Preparation of test solution

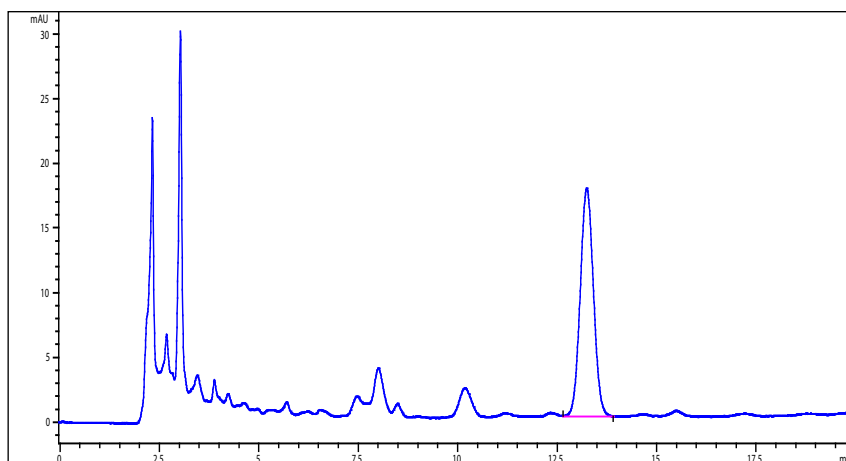
Cut the pills into pieces, accurately weigh 0.8 g in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 60 minutes, allow to cool, weigh again, replenish the lost weight with methanol, shake well, and filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-0.11% acetic acid (40:60)
- Detector wavelength: 238 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Hesperidin	4.332	13.33	16.75	396.5	7322	1.01

# Renshen Zaizao Pills (*Renshen Zaizao Wan*) – 人参再造丸

## Sample source

Commercially available Renshen Zaizao Pills

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200208)

## Preparation of test solution

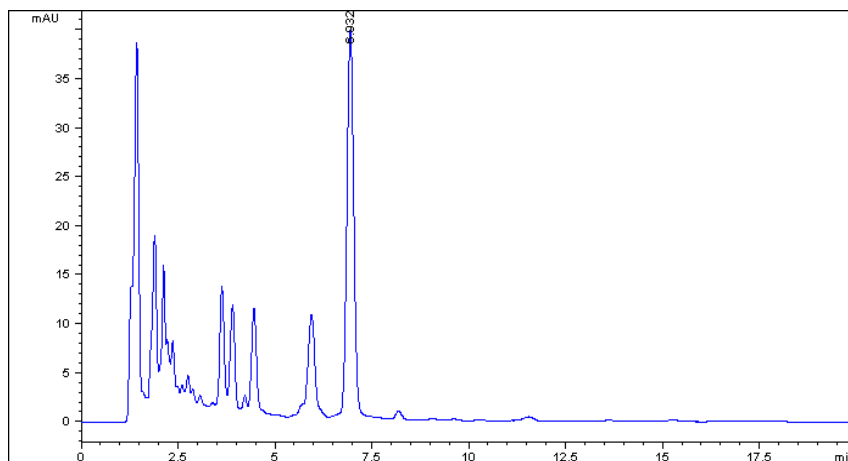
Cut the pills into pieces, mix well, accurately weigh 5 g in a stoppered conical flask, accurately add 50 mL of a mixture of hydrochloric acid and methanol (1:100), stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with a mixture of hydrochloric acid and methanol (1:100), shake well and filter. Accurately measure 25 mL of the filtrate, concentrate to about 10 mL, and apply to a neutral alumina column. Elute with 25 mL of ethanol, and collect the eluent in a 50 mL volumetric flask, dilute with ethanol to volume, shake well, filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (993967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.05 mol/L potassium dihydrogen phosphate (28:72)
- Detector wavelength: 345 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine		6.932	39.23	478.1	7558	1.03

# Honeysuckle Stem (*Caulis Lonicerae Japonicae*) – 忍冬藤

## Sample source

Commercially available Honeysuckle Stem (Zhejiang)

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110753-200212)

## Preparation of test solution

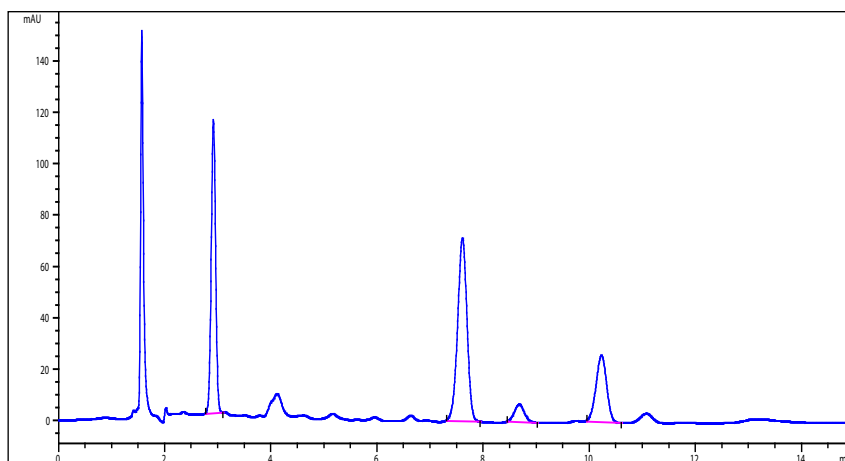
Accurately weigh 0.4 g of the powder in a stoppered conical flask, accurately add 10 mL of 50 % methanol, weigh, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 50 % methanol, mix well and filter.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.4% phosphoric acid (10:90)
- Detector wavelength: 327 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	5.343	7.612	71.29	877.4	9114	0.95

# Cistanche Herb (*Herba Cistanches*) – 肉苁蓉

## Sample source

Commercially available Desert-living Cistanche

## Chemical reference substances

Echinacoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111670-200401)

## Preparation of test solution

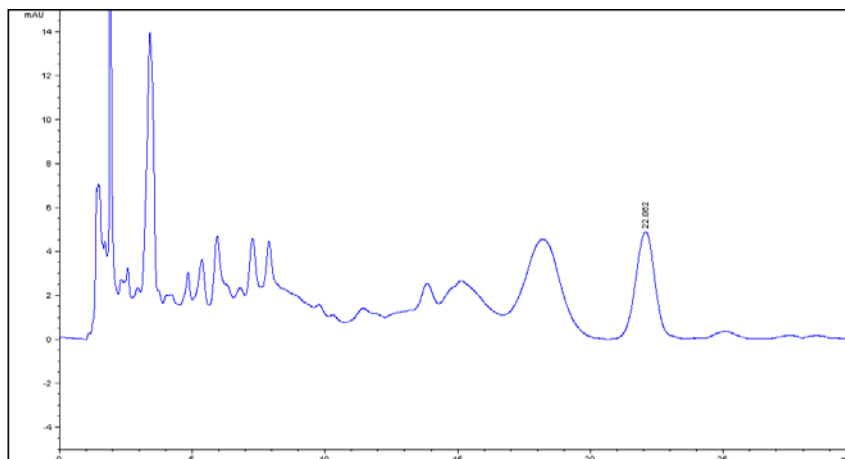
Accurately weigh 1 g of the powder in a 100 mL amber volumetric flask. Accurately add 50 % methanol, stopper tightly, weigh and allow to soak for 30 minutes. Treat ultrasonically for 50 minutes (below 50 °C), allow to cool, weigh again, replenish the lost weight with 50 % methanol, mix well and filter, and store the filtrate in an amber flask.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1% formic acid (26:74)
- Detector wavelength: 330 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Echinacoside	13.708	22.062	4.87	243.4	4528	0.98



# Cassia Bark (*Cortex Cinnamomi*) – 肉桂

## Sample source

Commercially available Cassia Bark

## Chemical reference substances

Cinnamic aldehyde (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110710-200212)

## Preparation of test solution

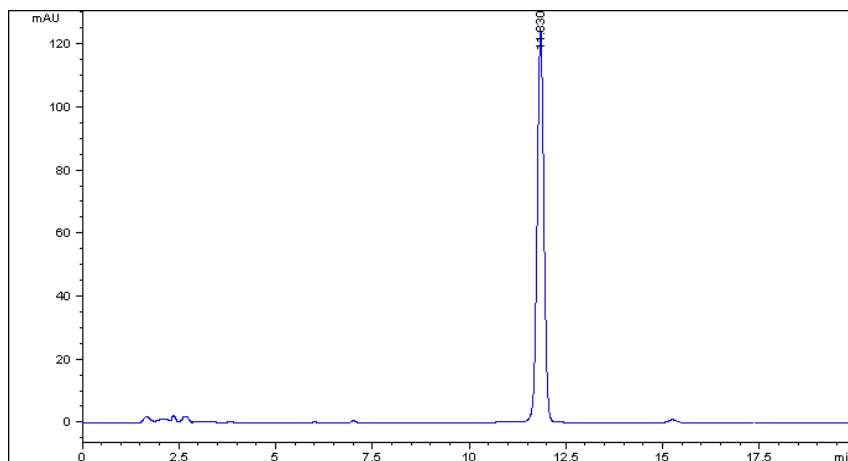
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 25 mL of methanol and weigh. Treat ultrasonically for 10 minutes, allow to stand overnight, treat ultrasonically for 10 minutes, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 1 mL of the filtrate in a 25 mL volumetric flask, add methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 μm (990967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (38:72)
- Detector wavelength: 290 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Cinnamic aldehyde	3.732	11.83	124.2	1497.9	23198	1.00

# Ruyi Jinhuang Powder (*Ruyi Jinhuang San*) – 如意金黃散

## Sample source

Commercially available Ruyi Jinhuang Powder

## Chemical reference substances

curcumin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110823-9802)

## Preparation of test solution

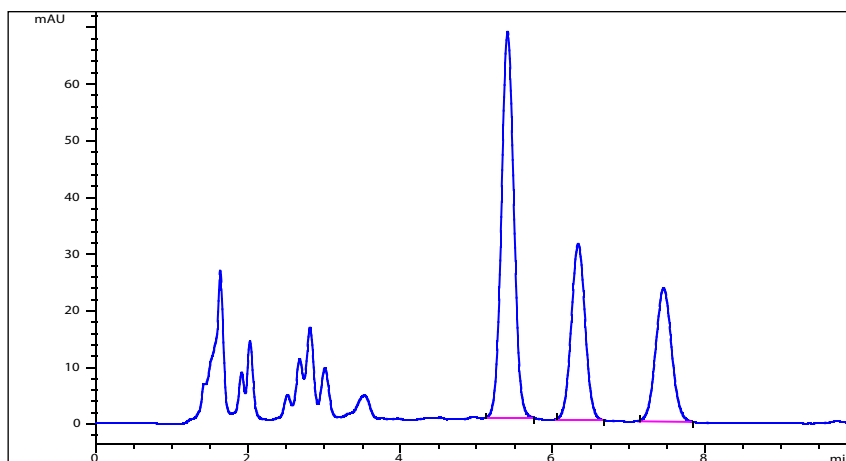
Accurately measure 0.25 g of the powder in a stoppered conical flask, accurately add 10 mL of methanol, stopper tightly and weigh. Allow to stand for 1 hour, weigh again, and replenish the lost weight with methanol, centrifuge, and use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-isopropanol-0.5% acetic acid (19:25:56)
- Detector wavelength: 430 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Curcumin	3.506	5.408	68.28	772.8	5407	1.03

# Rukuaixiao Tablets (*Rukuaixiao Pian*) – 乳块消片

## Sample source

Commercially available Rukuaixiao Tablets

## Chemical reference substances

sodium danshensu (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110855-200203)

## Preparation of test solution

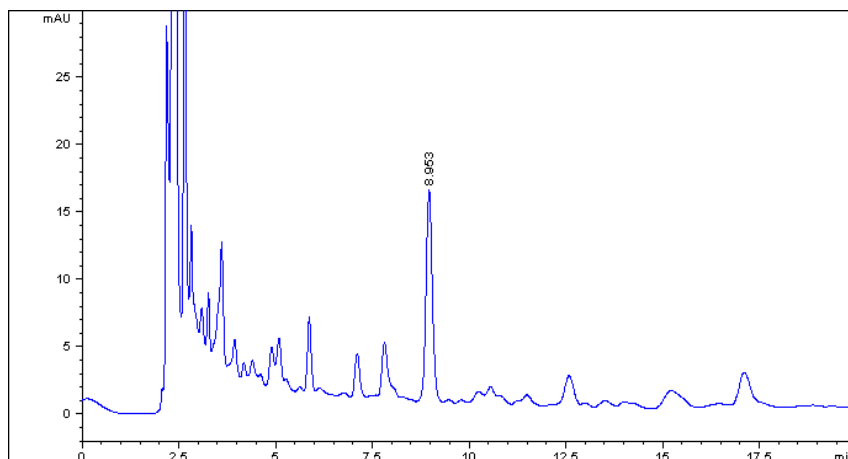
Remove the coatings from 10 tablets and weigh accurately. Grind to a fine powder, accurately weigh 0.15 g in a centrifugal tube, add 2 mL of water and 0.75 g of neutral alumina (100-200 mesh), and mix well. Wash with two 10 ml quantities of water, centrifuge, discard the washings, and extract by stirring with three 4 ml quantities of 5 % oxalic acid. Centrifuge, combine the oxalic acid solutions in a 25 mL volumetric flask, and dilute to volume with 5 % oxalic acid. Mix well and filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-methanol-1.45% glacial acetic acid (0.5:9:91)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Danshensu	2.581	8.953	15.74	179.3	15168	1.07

# Sanbao Capsules (*Sanbao Jiaonang*) – 三宝胶囊

## Sample source

Commercially available Sanbao Capsules

## Chemical reference substances

Protocatechuic aldehyde (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110810-200205)

## Preparation of test solution

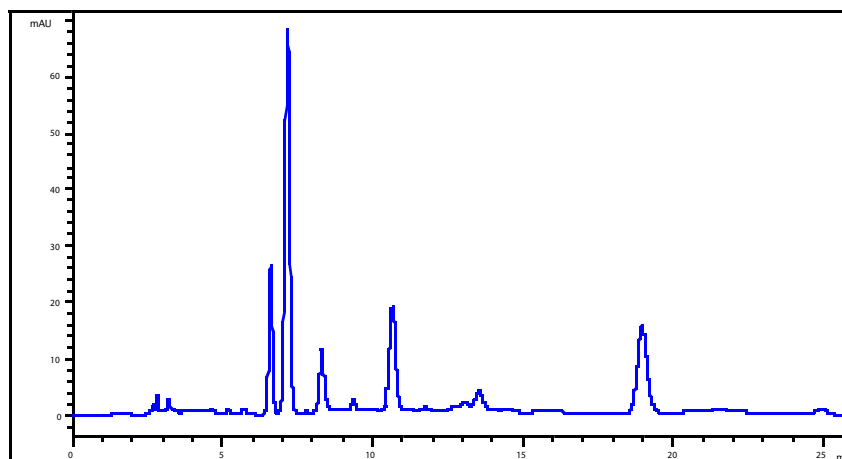
Accurately weigh the contents of 20 capsules, mix well, accurately weigh 0.8 g in a stoppered conical flask, accurately add 20 mL of methanol, weigh. Heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, shake well and filter. Accurately measure 10 mL of the filtrate and evaporate to dryness. Dissolve the residue in 10 mL of water and adjust pH to 2 with dilute hydrochloric acid TS, extract with four 10 ml quantities of ether, combine the ether extracts, evaporate the ether and dissolve the residue in methanol, transfer to a 10 mL volumetric flask, add methanol to volume, shake well, filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (518925-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: 0.1% acetic acid-methanol (87:13)
- Detector wavelength: 279 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP $T_r$
protocatechuic aldehyde	18.964	15.36	349.3	16546	1.08

# Sanjin Tablets (*Sanjin Pian*) – 三金片

## Sample source

Commercially available Sanjin Tablets

## Chemical reference substances

Madecassoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1110893-200201)

## Preparation of test solution

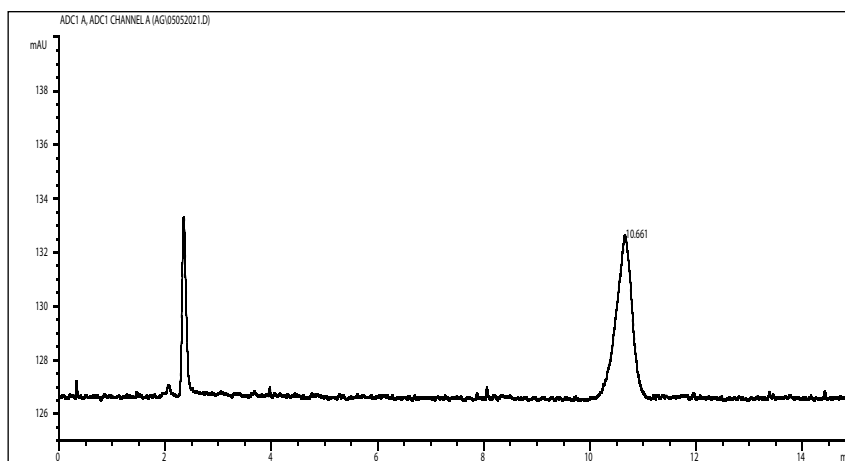
Remove the coatings from 30 tablets and grind to a fine powder. Accurately weigh 1.5 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol, weigh. Treat ultrasonically for 45 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 25 mL of the filtrate, evaporate to dryness, dissolve the residue in 20 mL of water, and extract with three 15 mL quantities of ammonia TS. Evaporate the n-butanol extracts to dryness, dissolve the residue in methanol and transfer to a 5 mL volumetric flask, dilute with methanol to volume, mix well.

## Chromatographic conditions

- Column: ZORBAX Extend C18 4.6×250 mm, 5 µm (770450-902)
- Column temperature: 40 °C
- Mobile phase: methanol-water (48:52)
- Evaporator tube temperature: 80 °C, Nebulizing temperature: 50 °C, Air flow rate: 1.5 SLM
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Autosampler (G1313A)
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD PL-ELS 1000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Madecassoside	3.298	10.661	6.07	127.1	6345	0.91

# Sanchi (*Radix et Rhizoma Notoginseng*) – 三七

## Sample source

Commercially available Sanchi (Yunnan province)

## Chemical reference substances

1. Notoginsenoside R<sub>1</sub>, 2. Ginsenoside Rg<sub>1</sub>, 3. Ginsenoside Rb<sub>1</sub> (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110745-200312, 2. 110703-200322)

## Preparation of test solution

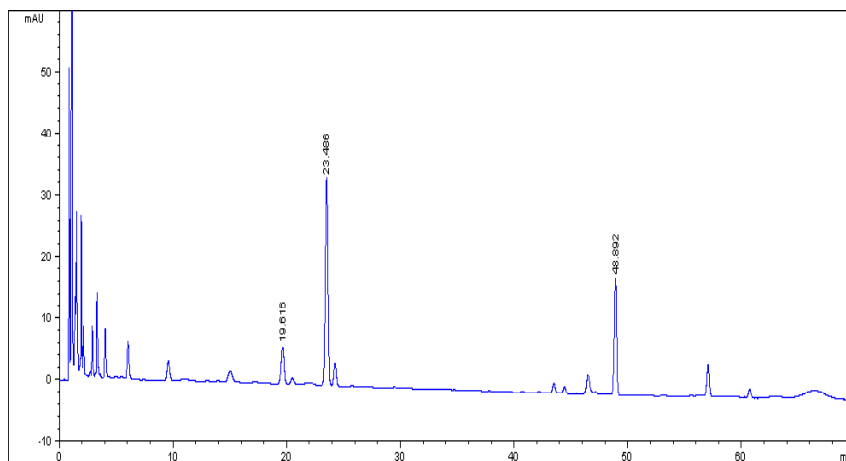
Accurately weigh 0.6 g of the powder, accurately add 50 mL of methanol, weigh and allow to stand overnight. Heat under reflux to boiling on a water bath at 80 °C for 2 hours, allow to cool and weigh again, replenish the lost solvent with methanol and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (993975-902)
- Column temperature: 25 °C
- Mobile phase: A: acetonitrile, B: water; 0~12 min, A: 19 %; 12~60 min, A: 19~36 %
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Notoginsenoside R <sub>1</sub>	15.346	19.616	5.82	104.1	27372	0.97
ginsenoside Rg <sub>1</sub>	18.571	23.486	33.52	536.3	50869	0.97
ginsenoside Rb <sub>1</sub>	39.743	48.892	18.74	266.7	277635	0.94

# Sanqi Tablets (*Sanqi Pian*) – 三七片

## Sample source

Commercially available Sanqi Tablets

## Chemical reference substances

1. Ginsenoside Rg1, 2. Ginsenoside Rb1, 3. Notoginsenoside R1 (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 1. 110745-200312, 3. 110703-200322)

## Preparation of test solution

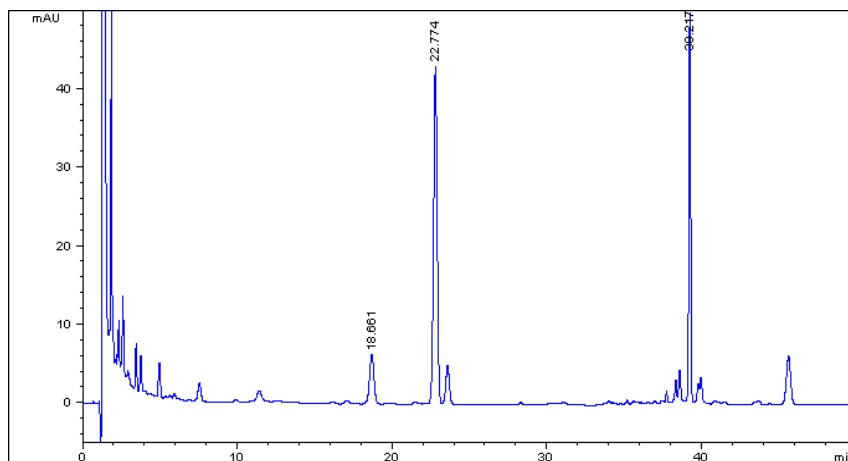
Accurately weigh 10 tablets, grind to a fine powder, accurately weigh 0.8 g in a stoppered conical flask, add 50 mL of methanol, weigh, allow to stand overnight, heat under reflux on a water bath at 80 °C for 2 hours, allow to cool, weigh again, replenish the lost weight with methanol, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 μm (993967-902)
- Column temperature: 25 °C
- Mobile phase: A: water, B acetonitrile; 0~12min, 19%B; 12~30 min, 19~25%B; 30~36min, 25~33%B
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Notoginsenoside R1	11.44	18.661	6.24	122.1	20967	0.96
Ginsenoside Rg1	14.183	22.774	42.96	693.2	46900	0.97
Ginsenoside Rb1	25.145	39.217	49.55	400.9	563641	0.95

# Sanqi Shangyao Tablets (*Sanqi Shangyao Pian*) – 三七伤药片

## Sample source

Commercially available Sanqi Shangyao Tablets

## Chemical reference substances

Naringin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110722-200309)

## Preparation of test solution

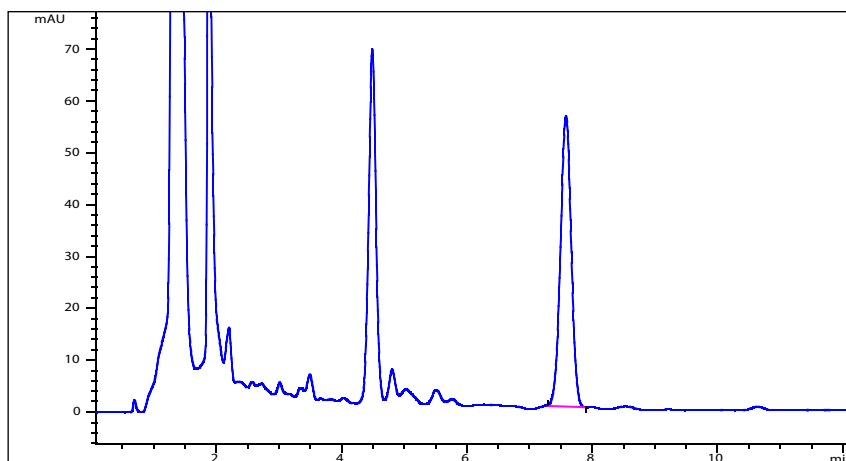
Remove the coatings from 20 tablets, grind to a fine powder, and accurately weigh 0.1 g of the powder in a stopper conical flask, accurately add 5 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and centrifuge, separate the supernatant and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (20:80)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Naringin	5.317	7.580	55.91	667.3	9359	0.98



# Sangju Ganmao Tablets (*Sangju Ganmao Pian*) – 桑菊感冒片

## Sample source

Commercially available Sangju Ganmao Tablets

## Chemical reference substances

forsythin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110821-200305)

## Preparation of test solution

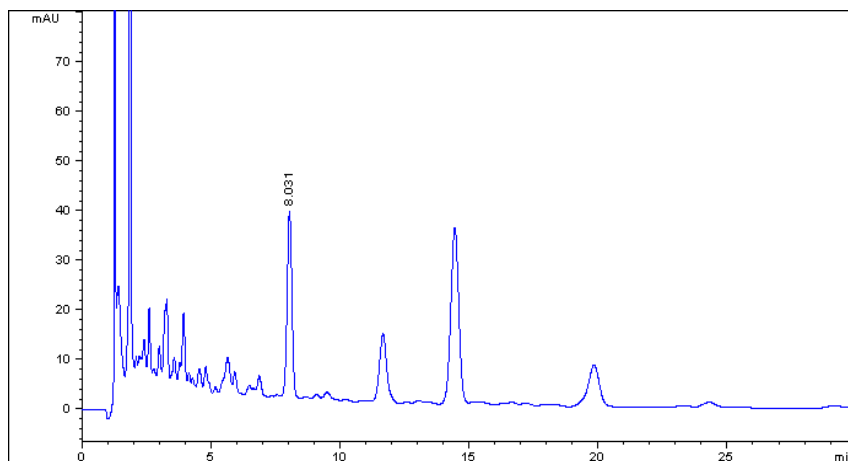
Weigh accurately 20 tablets, removed sugar coats, pulverize to fine powder. Weigh accurately 2 g of the powder in a stopper conical flask, add accurately 25 ml of methanol, stopper tightly and weigh, ultrasonicate for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Exactly measure 5 ml of the successive filtrate, evaporate to dryness, dissolve the residue in 20 ml of water, extract with five 20-ml quantities of chloroform, combine the chloroform extracts, evaporate to dryness, dissolve the residue in 50% methanol, and transfer to a 5 ml volumetric flask, dilute with 50% methanol to volume, shake well. Centrifuge, use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (25:75)
- Detector wavelength: 230 nm
- Flow rate: 1.0 ml/min
- Injection volume: 10 µl

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Forsythin	4.354	8.031	37.73	487.4	9249	0.97

# Mulberry Leaf (*Folium Mori*) – 桑叶

## Sample source

Commercially available Mulberry Leaf

## Chemical reference substances

Rutin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 100080-200306)

## Preparation of test solution

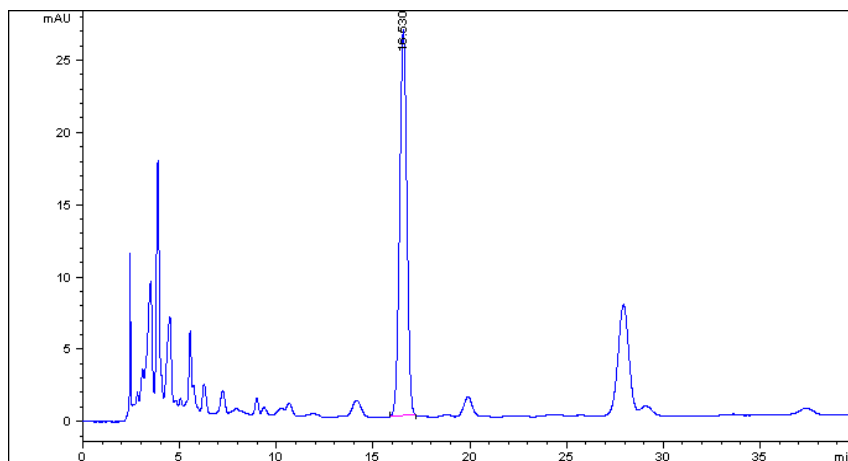
Accurately weigh 1 g of the fine powder in a round-bottom flask, add 50 mL of methanol, heat under reflux for 30 minutes, filter, extract the residue with two 50 ml quantities of methanol and combine the filtrates. Evaporate the solvent in vacuum, dissolve the residue in methanol and transfer to a 25 mL volumetric flask, dilute to volume, and mix well. Filter with a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-0.5% phosphoric acid (38:62)
- Detector wavelength: 358 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Rutin	5.612	16.53	26.73	694.0	9461	0.99

# Asiatic Cornelian Cherry Fruit (*Fructus Corni*) – 山茱萸

## Sample source

Commercially available Asiatic Cornelian Cherry Fruit

## Chemical reference substances

Loganin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111640-200401)

## Preparation of test solution

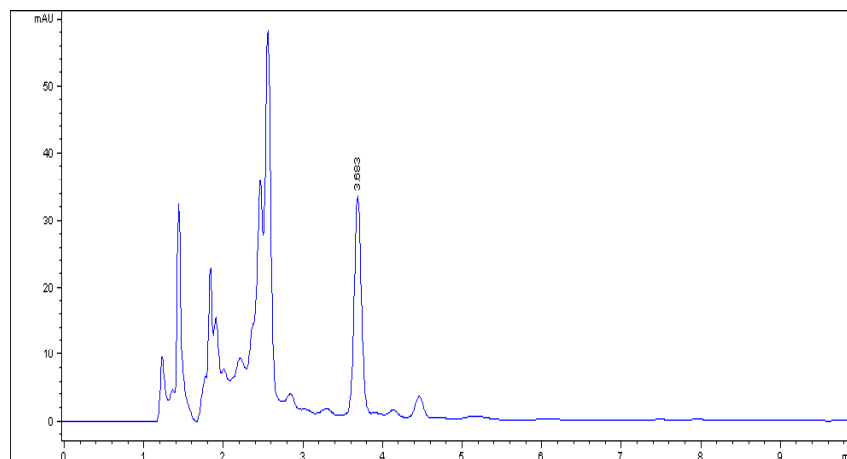
Accurately weigh 0.1 g of the powder in a stoppered conical flask, accurately add 25 mL of 80 % methanol and weigh, heat under reflux for 1 hour, cool and weigh accurately again, replenish the lost solvent with 80 % methanol, mix well and filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (15:85)
- Detector wavelength: 240 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Loganin	1.456	3.683	32.64	202.7	8231	1.04

# Shaoshangling Tincture (*Shaoshangling Ding*) – 烧伤灵酊

## Sample source

Commercially available Shaoshangling Tincture

## Chemical reference substances

Emodin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110756-200210)

## Preparation of test solution

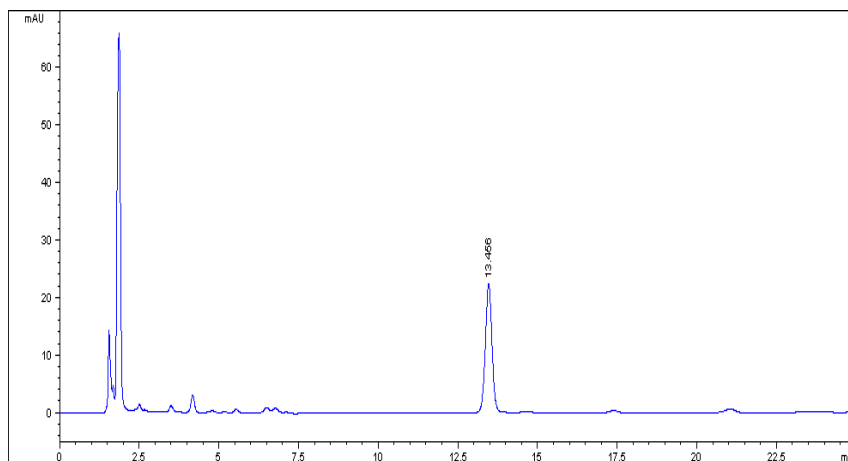
Accurately measure 2 mL of the tincture in an evaporating dish, add 1 g of silica gel (60-160 mesh), evaporate to dryness on a warm water bath. Apply to a column packed with dry silica gel (2 g, 15 mm in inner diameter), elute in vacuum with 90 mL of a mixture of petroleum ether (60-90 °C), formate acetate and formic acid (100:100:2), collect the eluent, evaporate to dry, dissolve the residue in a quantity of methanol. Transfer to a 100 mL volumetric flask, dilute with methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1% phosphoric acid (70:30)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Emodin	7.971	13.456	22.37	321.0	21030	1.01

# Common Cnidium Fruit (*Fructus Cnidii*) – 蛇床子

## Sample source

Commercially available Common Cnidium Fruit (Zhejiang province)

## Chemical reference substances

Osthole (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110822-200305)

## Preparation of test solution

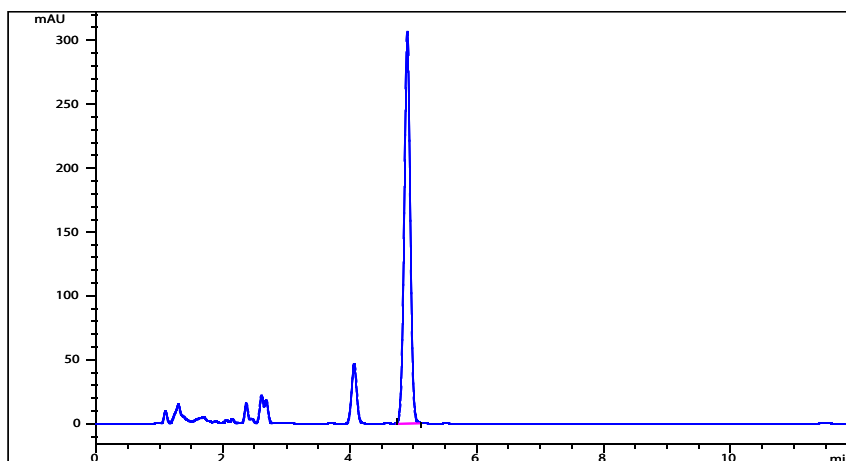
Accurately weigh 0.1 g of the powder in a stoppered conical flask, accurately add 25 mL of dehydrated ethanol, accurately weigh, allow to stand for 2 hours and treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost weight with dehydrated ethanol and mix well. Accurately measure 5 mL of the supernatant in a 10 mL volumetric flask, dilute with dehydrated ethanol to volume and mix well. Filter with a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (65:35)
- Detector wavelength: 322 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Osthole	3.089	4.906	306.38	2006.7	13150	0.99

# Blackberrylily Rhizome (*Rhizoma Belamcandae*) – 射干

## Sample source

Commercially available Blackberrylily Rhizome

## Chemical reference substances

Irisfloreantin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1557-200101)

## Preparation of test solution

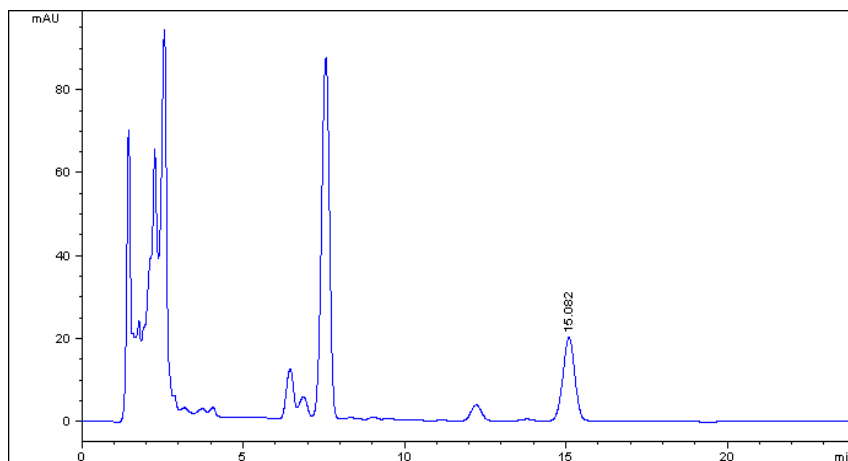
Accurately weigh 0.2 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol and weigh. Heat under reflux for 1 hour, allow to cool and weigh again, replenish the lost weight with methanol, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-0.2%phosphoric acid (52:48)
- Detector wavelength: 266 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Irisfloreantin	9.054	15.082	20.06	514.3	7956	0.98

# Shenjing Zhike Pills (*Shenjing Zhike Wan*) – 参精止渴丸

## Sample source

Commercially available Shenjing Zhike Pills

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110752-200209)

## Preparation of test solution

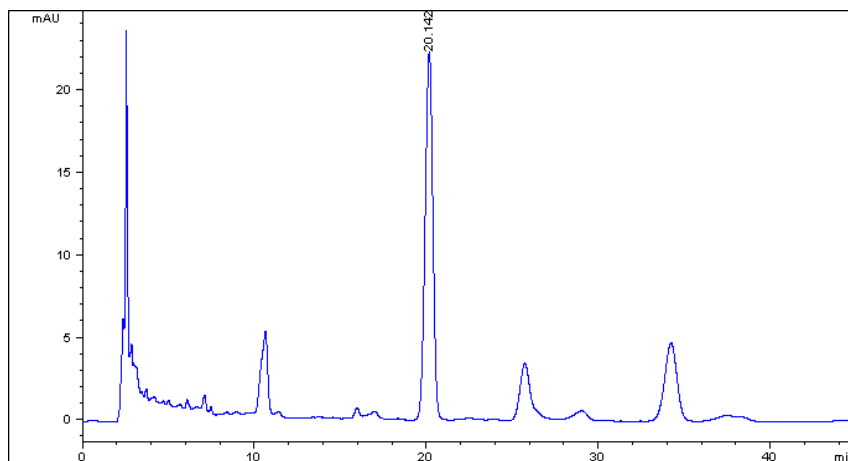
Grind the pills to a fine powder, accurately weigh 1.1 g of the powder in a Soxhlet extractor, add a quantity of ether, heat under reflux for 1 hour. Discard the ether extract and evaporate the remaining solvent in the residue, add a quantity of methanol, heat under reflux for 3 hours. Transfer the extract, concentrate when necessary, to a 50 mL volumetric flask, dilute with methanol to volume and mix thoroughly.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 μm (880975-902)
- Column temperature: 40 °C
- Mobile phase: methanol-25 mmol/L phosphoric acid (containing 0.18 % triethylamine) (20:80)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Inject volume: 2 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	7.057	20.142	22.28	689.5	9736	0.95

# Shenqi Wuweizi Tablets (*Shenqi Wuweizi Pian*) – 参芪五味子片

## Sample source

Commercially available Shenqi Wuweizi Tablets

## Chemical reference substances

Schisandrin A (National Institute for the Control of Pharmaceutical and Biological Products, Batch number (0764-200005))

## Preparation of test solution

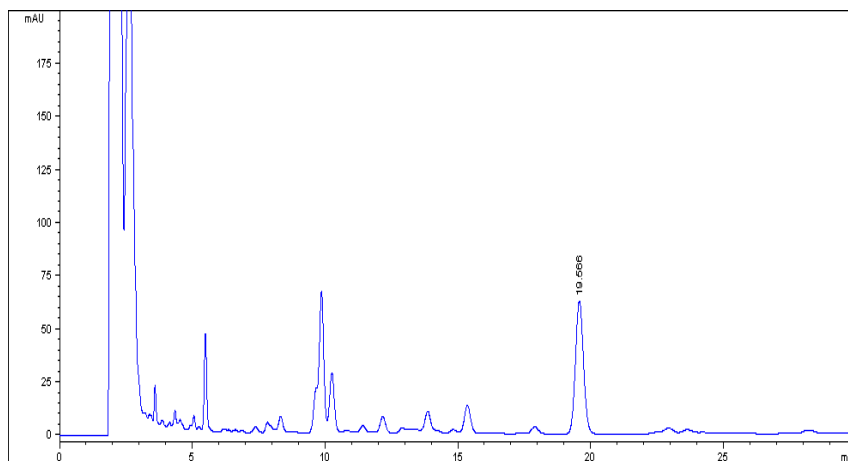
Remove the coatings from 20 tablets, grind to a fine powder. Accurately weigh 1 g in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly, and weigh. Treat ultrasonically for 20 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well, centrifuge, and use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water-acetic acid (64:35:1)
- Detector wavelength: 249 nm
- Flow rate: 1.0 mL/min
- Inject volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Schisandrin A	6.826	19.566	62.66	1318.5	20360	1.06



# Shensu Pills (*Shensu Wan*) – 参苏丸

## Sample source

Commercially available Shensu Pills

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110752-200209)

## Preparation of test solution

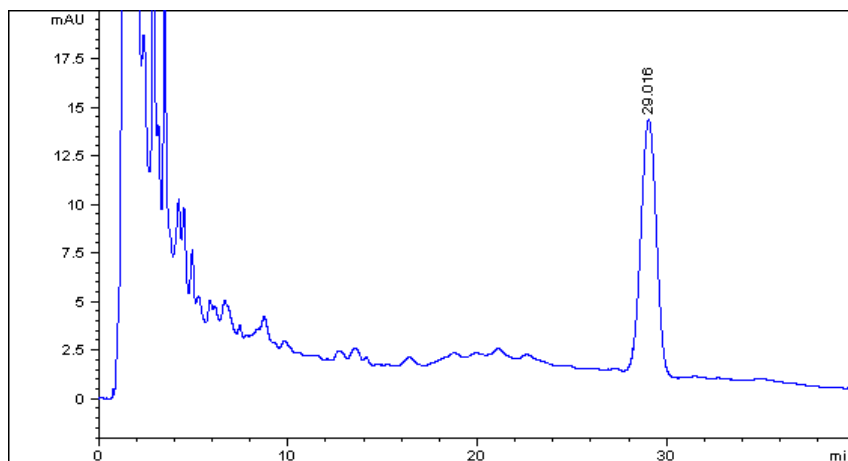
Grind the pills to a fine powder, accurately weigh 2 g in a stoppered conical flask, accurately add 25 mL of dilute ethanol TS, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with dilute ethanol TS. Filter the supernatant and use the filtrate as the test solution..

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (17:83)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	18.344	29.016	13.10	737.3	5933	0.96

# Shengxue Pills (*Shengxue Wan*) – 生血丸

## Sample source

Commercially available Shengxue Pills

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110713-200208)

## Preparation of test solution

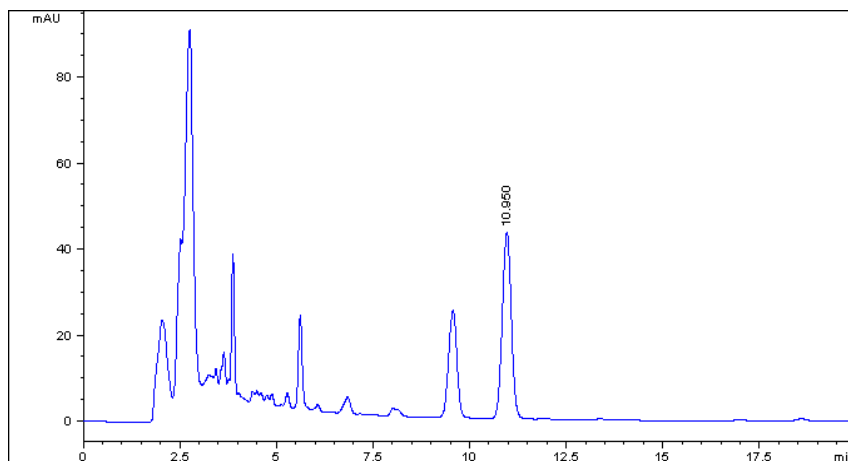
Grind the pills to a fine powder, accurately weigh 3 g of the powder in a Soxhlet extractor, add 40 mL of a mixture of methanol and hydrochloric acid (100:1), allow to soak overnight, add a quantity of methano, and heat under reflux until the extract is colorless. Allow to cool, concentrate the methanol extracts and transfer to a 50 mL volumetric flask, add methanol to volume, mix well and filter. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-(5 mmol/L sodium dihydrogen phosphate and 17 % sodium dodecylsulfonate) (50:50)
- Detector wavelength: 345 nm
- Flow rate: 1.0 mL/min
- Inject volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	3.380	10.95	43.43	709.0	10231	1.03

# Shiquan Dabu Pills (*Shiquan Dabu Wan*) – 十全大补丸

## Sample source

Commercially available Shiquan Dabu Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

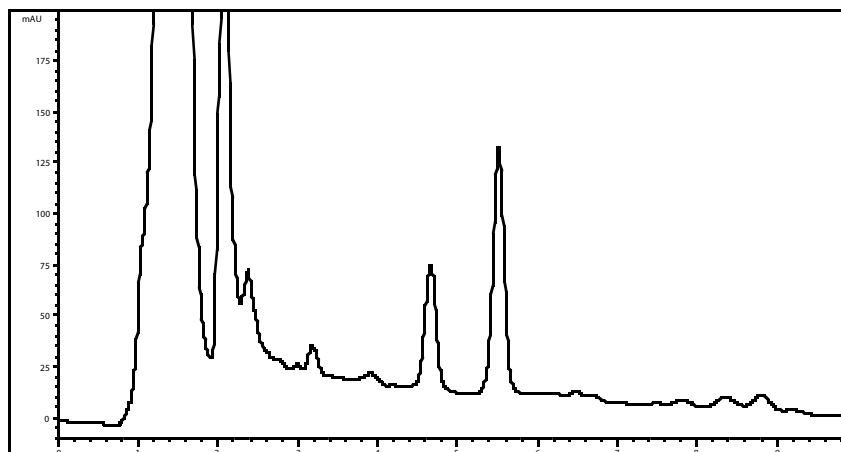
Grind the pills to a fine powder, accurately weigh 1.0 g of the powder in a stoppered conical flask, accurately add 25 mL of dilute ethanol TS, stopper tightly and weigh. Treat ultrasonically for 60 minutes, allow to cool, weigh again, replenish the lost weight with dilute ethanol TS, mix well and centrifuge. Use the filtrate of the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (16:84)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Paeoniflorin		5.515	19.95	1200.4	7287	0.97

# Shearer's Pyrrosia Leaf (*Folium Pyrrosiae*) – 石 韦

## Sample source

Commercially available Shearer's Pyrrosia Leaf (Anhui)

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number :110753-200212)

## Preparation of test solution

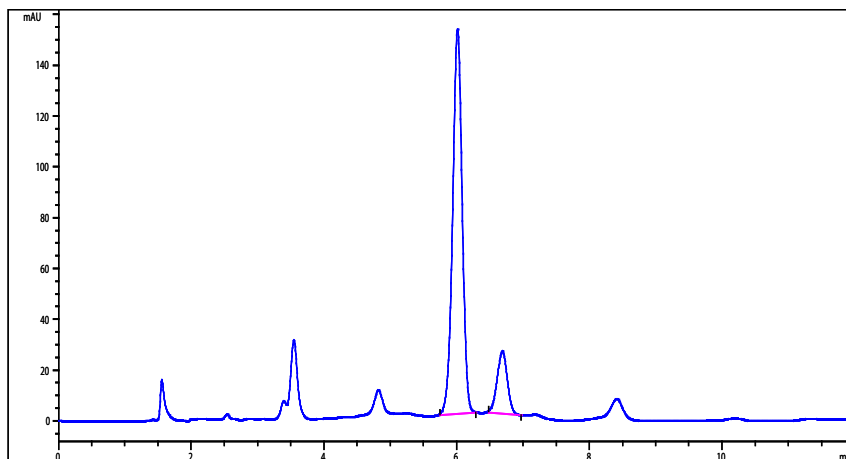
Accurately weigh 0.08 g of the powder in a stoppered conical flask, accurately add 10 mL of 50 % methanol, weigh, treat ultrasonicate for 45 minutes, allow to cool, weigh again, compensate the lost weight with 50 % methanol, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (11:89)
- Detector wavelength: 326 nm
- Flow rate: 1.0 mL/min
- Inject volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	4.012	6.015	151.48	1525.9	8485	0.96

# Shugan Hewei Pills (*Shugan Hewei Wan*) – 舒肝和胃丸

## Sample source

Commercially available Shugan Hewei Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

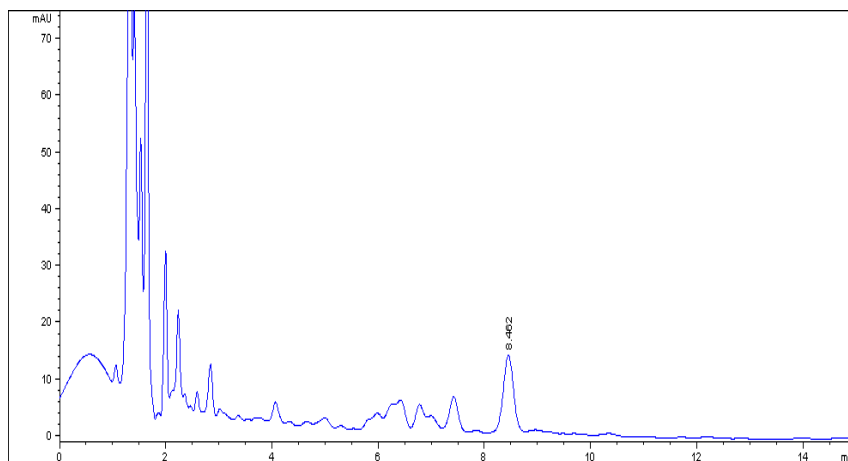
Cut the pills into pieces. Accurately weigh 0.75 g in a stoppered conical flask, accurately add 25 mL of dilute ethanol TS, stopper tightly, weigh and treat ultrasonically for 30 minutes. Allow to cool, weigh again and replenish the lost weight with dilute ethanol TS, mix well, centrifuge and filter the supernatant, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.05 mol/L potassium dihydrogen phosphate (14:86)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	4.641	8.462	13.53	176.6	9701	1.00

# Shugan Pills (*Shugan Wan*) – 舒肝丸

## Sample source

Commercially available Shugan Pills

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

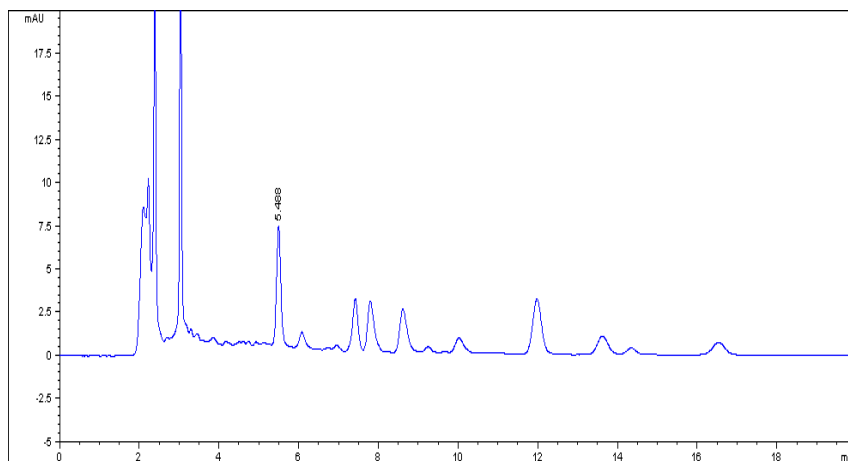
Grind the pills to a fine powder, accurately weigh 1 g, in a stoppered conical flask, accurately add 50 mL of dilute ethanol TS, stopper tightly, weigh and treat ultrasonically for 45 minutes. Allow to cool, weigh again and replenish the lost weight with dilute ethanol TS, mix well and filter. Accurately measure 5 mL of the filtrate and evaporate to dryness, dissolve the residue in 5 mL of water and apply to a GDX-201 macroporous resin column (1.0 cm in inner diameter and 12 cm in length). Elute with 100 mL of 30 % methanol, and collect the eluents. Evaporate to dryness, dissolve the residue in methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-phosphate BS (0.05 mol/L disodium hydrogen phosphate:0.05 mol/L sodium dihydrogen phosphate = 1:5) (20:80)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	1.195	5.488	6.92	51.0	13106	1.08

# Shuanghuanglian Granules (*Shuanghuanglian Keli*) – 双黄连颗粒

## Sample source

Commercially available Shuanghuanglian Granules

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0715-200212)

## Preparation of test solution

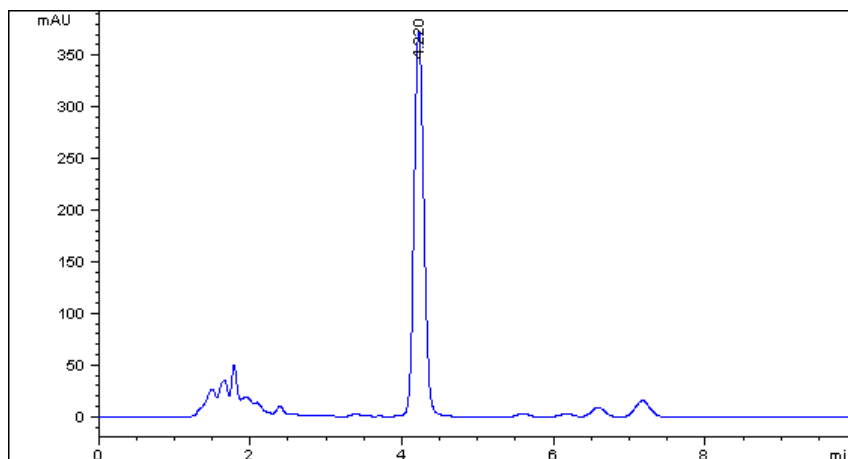
Grind the granules to a fine powder. Accurately weigh 0.5 g in a 50 mL volumetric flask, add a quantity of 50 % methanol, treat ultrasonically for 20 minutes, allow to reach room temperature, dilute with 50 % methanol to volume, shake well, filter. Accurately measure 2 mL of the filtrate in a 10 mL volumetric flask, dilute with 50 % methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: methanol-2 % glacial acetic acid (50:50)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	1.814	4.220	340.85	3373.8	4868	1.05

# Shuanghuanglian Mixture (*Shuanghuanglian Koufuye*)

双黄连口服液

## Sample source

Commercially available Shuanghuanglian Mixture

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

## Preparation of test solution

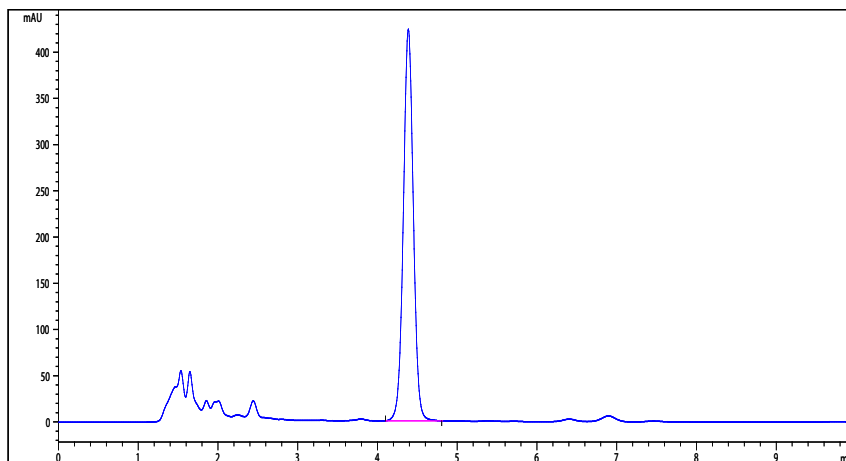
Accurately measure 0.2 mL of the mixture in a 10 mL volumetric flask, add a quantity of 50 % methanol, treat ultrasonically for 20 minutes, allow to reach room temperature, dilute with 50 % methanol to the volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water-glacial acetic acid (50:50:1)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Baicalin	2.656	4.387	423.35	3677.7	6208	1.02



# Shuanghuanglian Mixture (*Shuanghuanglian Koufuye*)

## 双黄连口服液

### Sample source

Commercially available Shuanghuanglian Mixture

### Chemical reference substances

Forsythin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110821-200305)

### Preparation of test solution

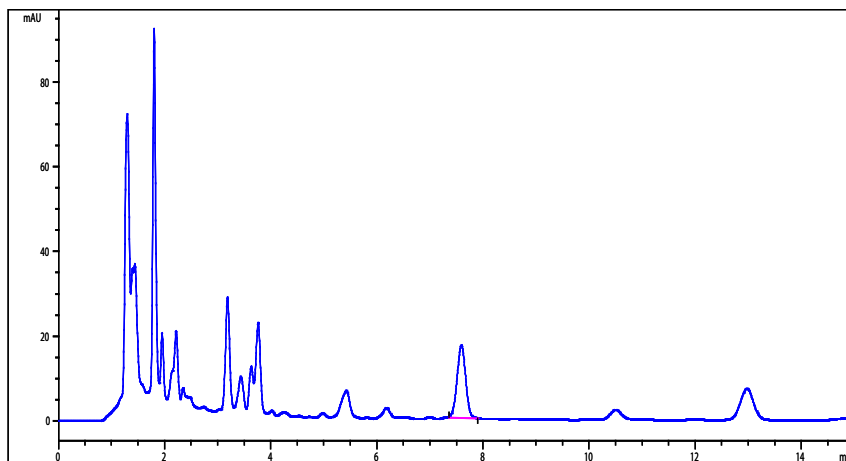
Accurately measure 1 mL of the mixture, apply to a column packed with neutral alumina (100-200 mesh, 6 g, 1 cm in inner diameter), elute with 40 mL of 70 % ethanol and collect the eluent. Evaporate to dryness and dissolve the residue in a quantity of 50 % methanol in a 5 mL volumetric flask, dilute to volume and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (25:75)
- Detector wavelength: 278 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Forsythin	5.330	7.596	17.07	192.7	10667	0.97

# Shuanghuanglian Mixture (*Shuanghuanglian Koufuye*)

双黄连口服液

## Sample source

Commercially available Shuanghuanglian Mixture

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110753-200212)

## Preparation of test solution

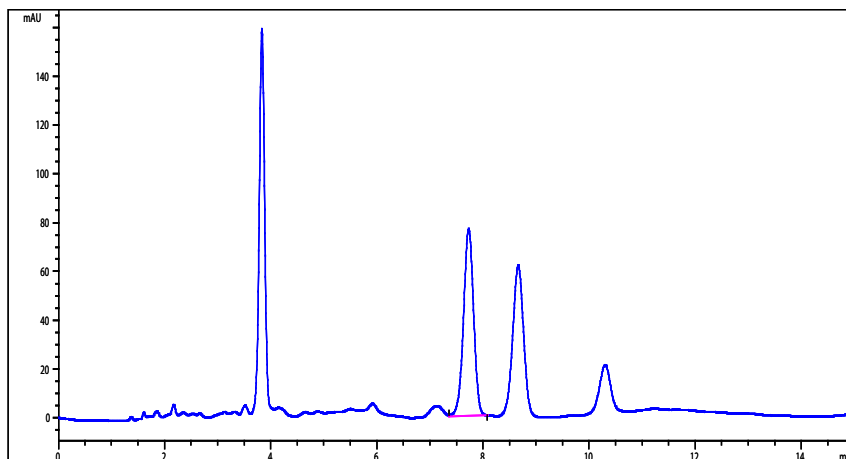
Accurately measure 2 mL of the mixture in a 50 mL volumetric flask, add water to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water-glacial acetic acid (20:80:1)
- Detector wavelength: 324 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	5.433	7.732	76.67	1009.2	8365	0.97

# Shuanghuanglian Tablets (*Shuanghuanglian Pian*) – 双黄连片

## Sample source

Commercially available Shuanghuanglian Tablets

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0715-200212)

## Preparation of test solution

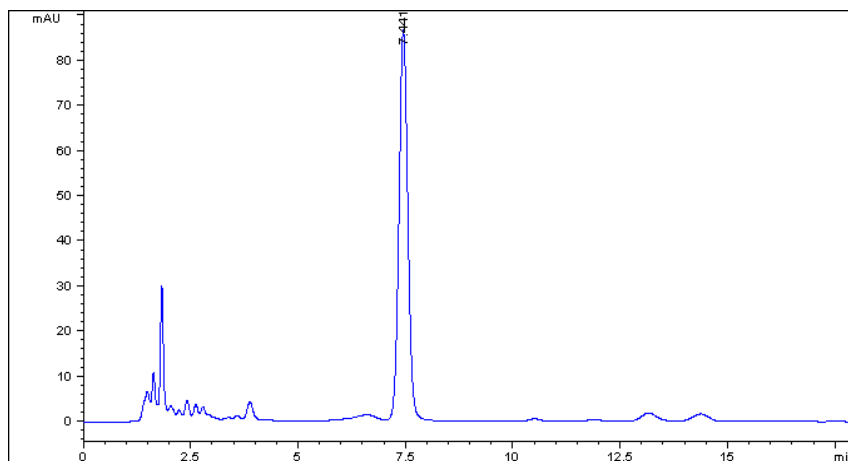
Grind the tablets to a fine powder, accurately weigh 0.2 g in a 50 mL volumetric flask, add a quantity of 50 % solution of methanol. Treat ultrasonically for 20 minutes, allow to cool, dilute with 50 % methanol to volume, mix well and filter. Transfer accurately 2 mL of the filtrate to a 10 mL volumetric flask, add 50 % methanol to volume, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-2 % glacial acetic acid (46:54)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	5.201	7.441	86.27	1245.3	6290	1.04

# Shuanghuanglian Tablets (*Shuanghuanglian Pian*) – 双黄连片

## Sample source

Commercially available Shuanghuanglian Tablets

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0753-200212)

## Preparation of test solution

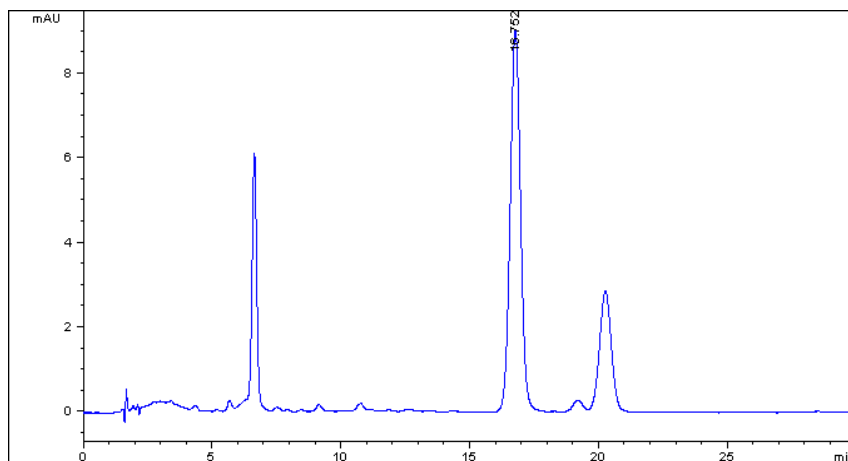
Grind the tablets to a fine powder, accurately weigh 0.2 g in a 50 mL volumetric flask, add a quantity of 50 % solution of methanol. Treat ultrasonicate for 20 minutes, allow to cool, dilute with 50 % methanol to volume, mix well and filter. Transfer accurately 2 mL of the filtrate to a 10 mL volumetric flask, add 50 % methanol to volume, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-1.18 % glacial acetic acid (13:87)
- Detector wavelength: 324 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	12.960	16.752	8.99	248.8	8720	1.03

# Silybum Marianum Fruit (*Fructus Silybi*) – 水飞蓟

## Sample source

Commercially available Fruit of Silybum Marianum

## Chemical reference substances

Silybin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110856-200203)

## Preparation of test solution

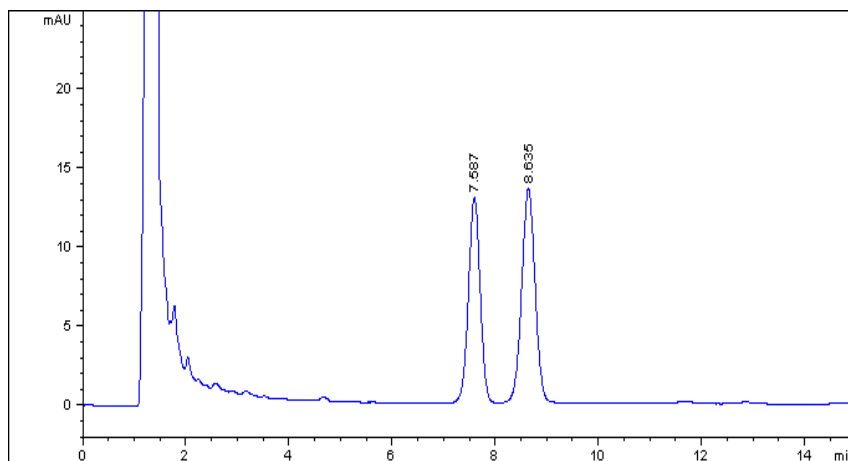
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of 75 % methanol, weigh and heat under reflux on a water bath for 30 minutes, allow to cool, weigh again and replenish the lost weight with 75 % methanol, mix well and allow to stand. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid (48:52:1)
- Detector wavelength: 287 nm
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Silybin	4.058	7.587	12.97	203.8	5537	0.98
Isosilybin	4.757	8.635	13.53	242.3	5529	1.00

# Sishen Pills (*Sishen Wan*) – 四神丸

## Sample source

Commercially available Sishen Pills

## Chemical reference substances

1. Psoralen, 2. Isopsoralen (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 110739-200309, 2. 110738-200309)

## Preparation of test solution

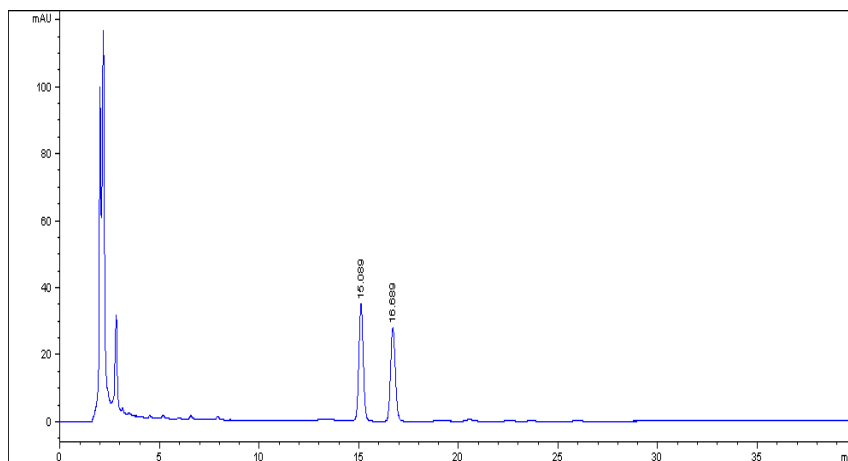
Grind the pills to a fine powder, accurately weigh 1 g in a stoppered conical flask, accurately add 100 mL of 70 % methanol, stopper tightly, and weigh. Treat ultrasonically for 20 minutes, allow to cool, weigh again, replenish the lost weight with 70 % methanol, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (33:67)
- Detector wavelength: 245 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Psoralen	5.036	15.089	34.9	531.5	23616	1.06
Isopsoralen	5.675	16.689	27.76	463.4	23625	1.09

# Siwu Mixture (*Siwu Heji*) – 四物合剂

## Sample source

Commercially available Siwu Mixture

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0736-200220)

## Preparation of test solution

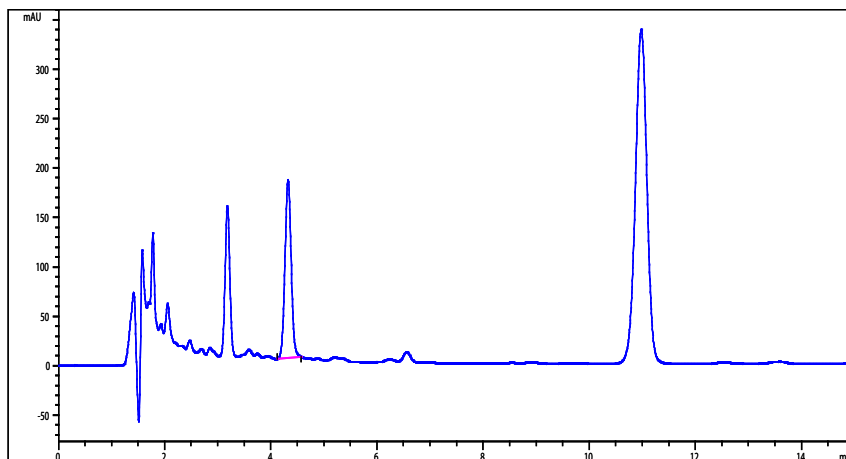
Mix the mixture well, accurately measure 0.4 mL of the mixture in a 10 mL volumetric flask, dilute with water to volume, shake well, and filter.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-isopropanol-acetic acid-water (25:2:2:71)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Inject volume: 10 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Paeoniflorin		4.326	179.97	1464.9	6770	1.05

# Sizheng Pills (*Sizheng Wan*) – 四正丸

## Sample source

Commercially available Sizheng Pills

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110721-200211)

## Preparation of test solution

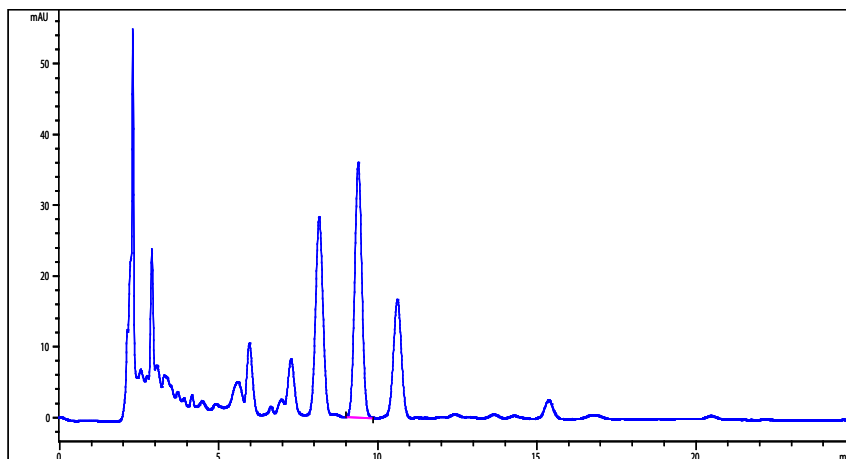
Cut the pills into pieces, accurately weigh 2 g in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly and weigh, treat ultrasonically for 45 minutes. Allow to cool, weigh again, replenish the lost weight with methanol, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 40  $^{\circ}\text{C}$
- Mobile phase: methanol-0.5% acetic acid (39:61)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Hesperidin	2.754	9.385	36.00	565.0	8317	1.02



# Songling Xuemaikang Capsules (*Songling Xuemaikang Jiaonang*)

## 松龄血脉康胶囊

### Sample source

Commercially available Songling Xuemaikang Capsules

### Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110752-200209)

### Preparation of test solution

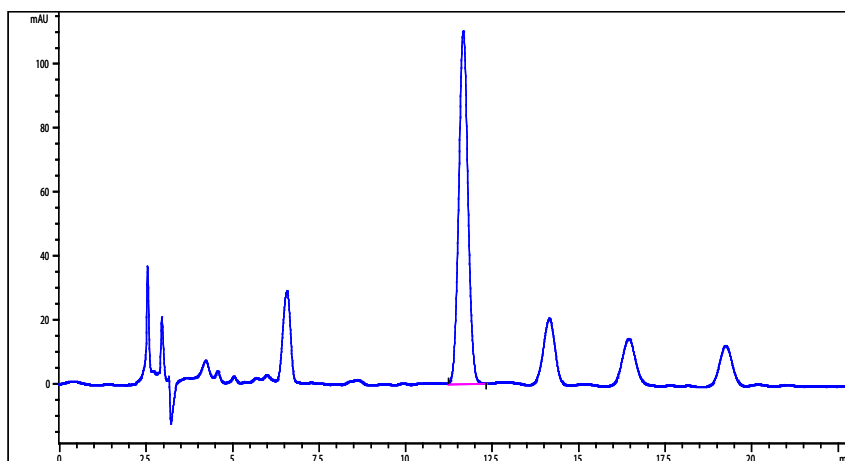
Accurately weigh about 0.15 g of the mixed contents in a stoppered conical flask, accurately add 50 mL of 50 % ethanol, stopper tightly, weigh and treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 50 % ethanol, mix well and filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-4 % acetic acid (20:80)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5  $\mu\text{L}$

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Puerarin	3.666	11.666	110.35	2055.5	9392	1.05

# Buckeye Seed (*Semen Aesculi*) – 娑罗子

## Sample source

Commercially available Buckeye Seed

## Chemical reference substances

Sodium aescine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 10346-0001)

## Preparation of test solution

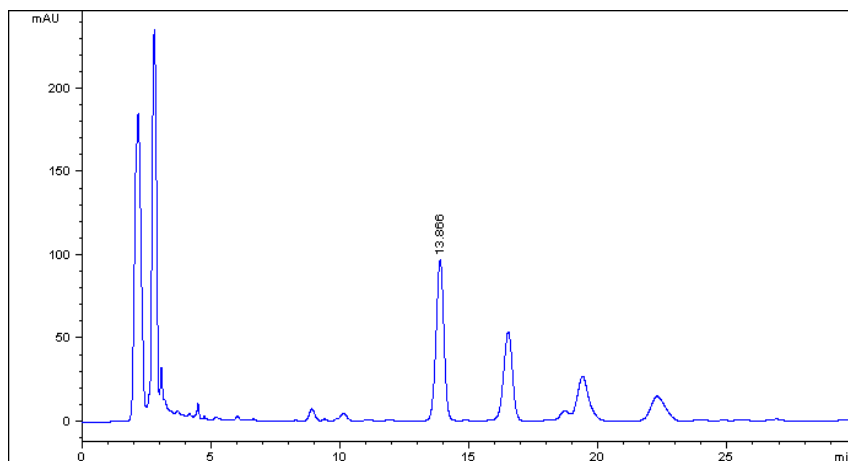
Accurately weigh 1 g of the powder in a Soxhlet extractor, heat under reflux in ether for 1 hour, then discard ether, and evaporate the ether to dryness. Transfer the residue and extractor to a stoppered conical flask, accurately add 50 mL of methanol, weigh, and treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost solvent with methanol and mix well, filter. Accurately measure 25 mL of the filtrate in an evaporating dish. Heat on a water bath at 40 °C and concentrate to suitable volume, transfer to a 10 mL volumetric flask, add methanol to volume, and mix well. Filter through millipore membrane (0.45 µm), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.2% phosphoric acid (37:63)
- Detector wavelength: 220 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Aescine	4.546	13.866	96.37	2021.0	10225	0.96

# Snow Lotus Herb (*Herba Saussureae Involucratae*) – 天山雪莲

## Sample source

Commercially available Snow Lotus Herb (Xinjiang)

## Chemical reference substances

1. Rutin, 2. Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 100080-200306, 2. 110753-200212)

## Preparation of test solution

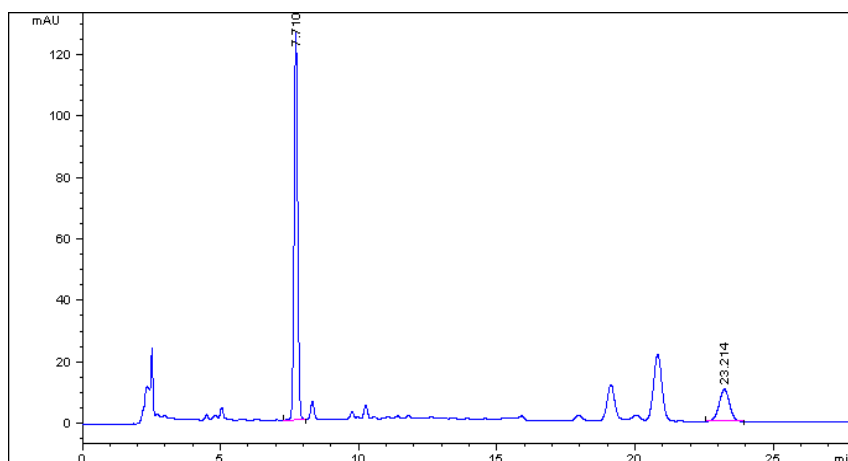
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 50 mL of 50 % methanol, weigh. Treat ultrasonically for 10 minutes, allow to cool, weigh again, replenish the lost weight with 50 % methanol, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 μm (880975-902)
- Column temperature: 25 °C
- Mobile phase: A. 0.4 % phosphoric acid, B. methanol; 0-10 min, 25 %B; 10-30 min, 25-38 %B
- Detector wavelength: 340 nm
- Flow rate: 1.0 mL/min
- Inject volume: 10 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Chlorogenic acid	2.084	7.710	126.44	1131.1	17833	1.02
rutin	8.285	23.21	10.57	283.9	18398	0.96

# Tiaojing Cuyun Pills (*Tiaojing Cuyun Wan*) – 调经促孕丸

## Sample source

Commercially available Tiaojing Cuyun Pills

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

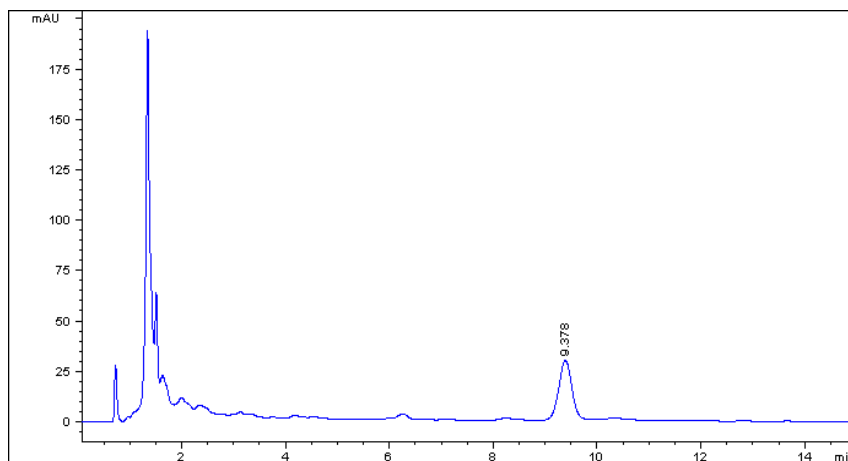
Grind the pills to fine powder, accurately weigh 1.5 g in a Soxhlet extractor, add a quantity of ether, heat under reflux for 3 hours, discard the ether extract and evaporate the remaining solvent in the residue. Put the residue and the extractor in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly, and weigh accurately. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, shake well and filter. Accurately measure 25 mL of the filtrate, and evaporate to dryness. Dissolve the residue in a quantity of water, apply to a D 101 macroporous resin column (1.5 cm in inner diameter, 12 cm in length), elute with water until the eluent is colorless, and then elute with 50 % ethanol. Discard the initial eluent, collect 100 mL of the successive eluent, evaporate to dryness, dissolve the residue in a quantity of methanol, transfer to a 25 mL volumetric flask, dilute with methanol to volume, and shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: methanol-water (26:74)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	6.815	9.378	29.29	504.6	6838	1.01

# Tongtian Mixture (*Tongtian Koufuye*) – 通天口服液

## Sample source

Commercially available Tongtian Mixture

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

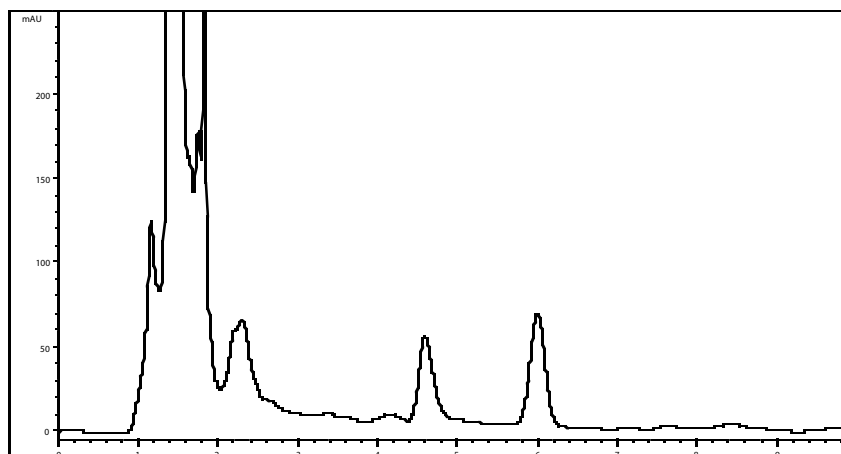
Accurately measure 2 mL of the mixture in a 25 mL volumetric flask, dilute with 50 % ethanol to volume and mix well. Centrifuge, use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (30:70)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Paeoniflorin		6.005	66.88	888.4	4695	0.97

# Tongxinluo Capsules (*Tongxinluo Jiaonang*) – 通心络胶囊

## Sample source

Commercially available Tongxinluo Capsules

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

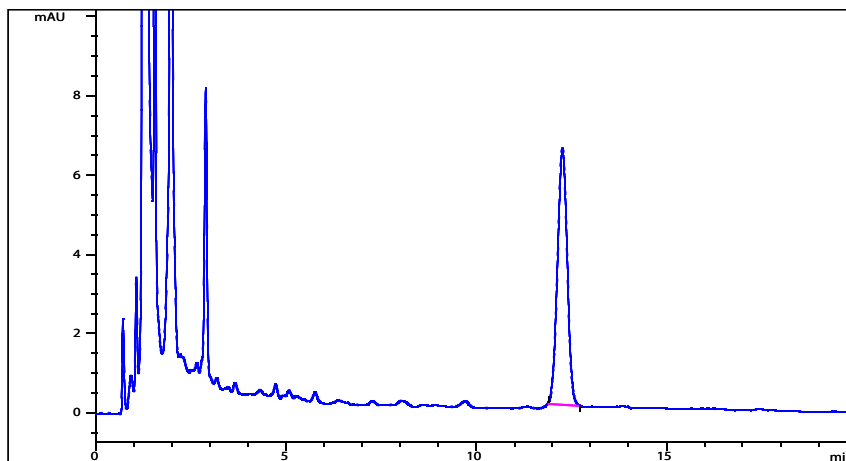
Grind the contents of the capsules to a fine powder, accurately weigh 0.1 g in a stoppered conical flask, add 10 mL of 70 % methanol, stopper tightly, weigh and treat ultrasonically for 50 minutes, allow to cool, weigh again, replenish the lost weight with methanol, shake well, and filter. Accurately measure 4 mL of the filtrate in a 10 mL volumetric flask, dilute with 70 % methanol to volume, shake well, filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (12:88)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	9.221	12.265	6.48	114.7	11281	0.99

# Tongxuan Lifei Pills (*Tongxuan Lifei Wan*) – 通宣理肺丸

## Sample source

Commercially available Tongxuan Lifei Pills

## Chemical reference substances

ephedrin hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

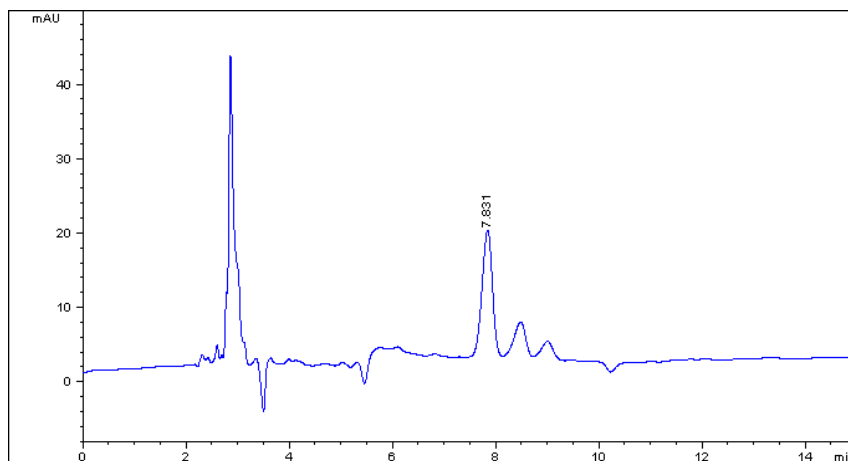
Grind the pills to fine powder, accurately weigh 2 g in a Soxhlet extractor, add 3 mL of concentrated ammonia TS, 10 mL of ethanol, and a quantity of ether, extract under reflux until the extract is colorless. Transfer the ether extract to an evaporating dish, wash the extractor and apparatus with ether, combine ether washings in the evaporating dish, and evaporate the ether. Dissolve the residue in a solution of hydrochloric acid in methanol (1:1000), and transfer to a 10 mL of volumetric flask, add a solution of hydrochloric acid in methanol (1:1000) to volume, mix well and filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-20 mmol/L potassium dihydrogen phosphate (pH 2.7) (3:97)
- Detector wavelength: 210 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ephedrin	2.123	7.831	16.71	236.1	7283	0.95

# Golden Larch Bark (*Cortex Pseudolaricis*) – 土荆皮

## Sample source

Commercially available Golden Larch Bark

## Chemical reference substances

pseudolaric acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110880-200202)

## Preparation of test solution

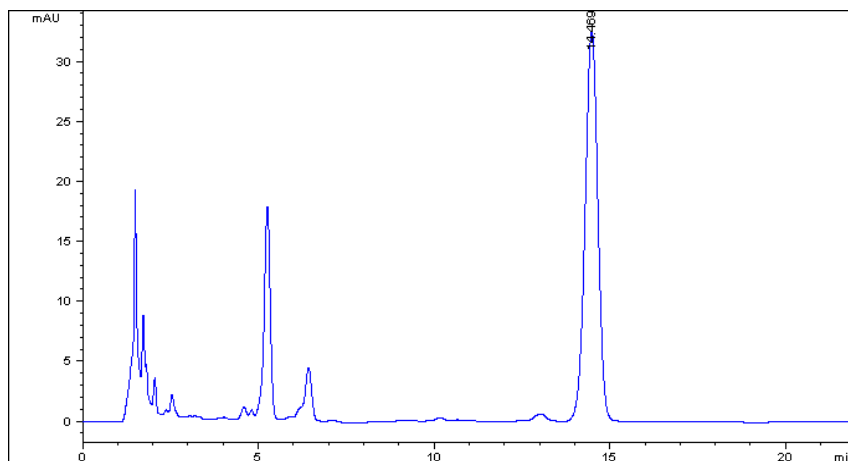
Accurately weigh 0.2 g of the powder in a stopper conical flask, accurately add 25 mL of methanol, weigh, heat on a water bath for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-906)
- Column temperature: 25 °C
- Mobile phase: methanol-1% glacial acetic acid (52:48)
- Detector wavelength: 260 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Pseudolaric acid	8.646	14.469	32.59	818.7	7889	0.96



# Fimbriate Orostachys Herb (*Herba Orostachyis Fimbriati*) – 瓦松

## Sample source

Commercially available Fimbriate Orostachys Herb

## Chemical reference substances

1. Quercetin, 2. Kaempferol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 0081-9905, 2. 0864-9901)

## Preparation of test solution

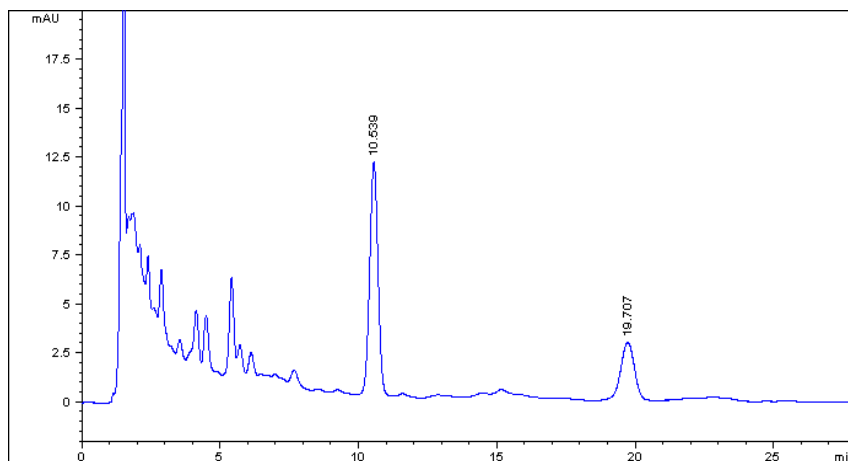
Accurately weigh 1 g of the fine powder in a stoppered conical flask, accurately add 50 mL of a mixture of methanol and 25 % hydrochloric acid solution (4:1), weigh, heat on a water bath for 1 hour, cool immediately, weigh again, replenish the lost weight with methanol, mix well, filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.5% phosphoric acid (46:54)
- Detector wavelength: 360 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Quercetin	6.026	10.539	11.93	247.2	5997	0.99
Kaempferol	12.138	19.707	2.93	98.1	8129	0.97

# Wanying Capsules (*Wanying Jiaonang*) – 万应胶囊

## Sample source

Commercially available Wanying Capsules

## Chemical reference substances

berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110713-200208)

## Preparation of test solution

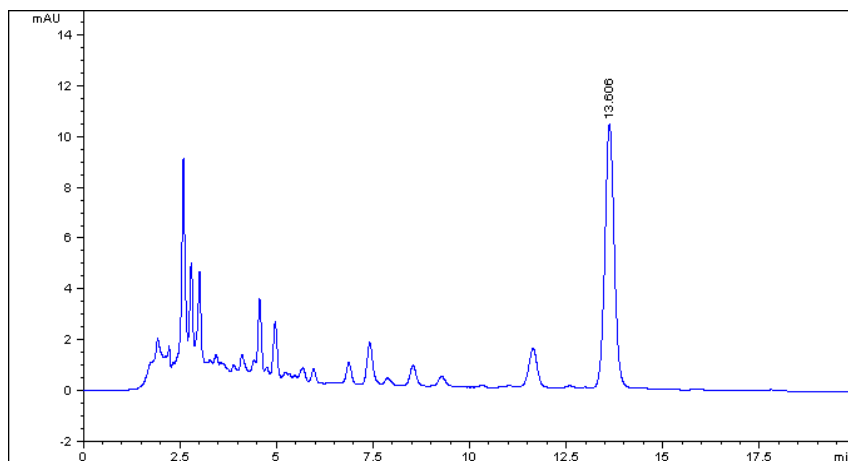
Grind the contents of the capsules to fine powder, accurately weigh 0.3 g. Add 30 mL of a mixture of hydrochloric acid and 70 % ethanol (1:100), heat under reflux for 1 hour, allow to cool, filter, and transfer the filtrate to a 50 mL volumetric flask. Wash the container and the residue with a mixture of hydrochloric acid and 70 % ethanol (1:100) several times, combine the washings in the same flask, and dilute to volume with a mixture of hydrochloric acid and 70 % ethanol (1:100). Mix well, centrifuge, accurately measure 1 mL of the supernatant in a 10 mL volumetric flask, dilute to volume with the mobile phase, and shake well.

## Chromatographic conditions

- Column: Reprosil Pur C18, 4.0×150 mm, 5 μm
- Column temperature: 25 °C
- Mobile phase: acetonitrile-33 mmol/L potassium dihydrogen phosphate (30:70)
- Detector wavelength: 265nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine	5.803	13.606	10.39	173.5	16103	1.04

# Weikangling Capsules (*Weikangling Jiaonang*) – 胃康灵胶囊

## Sample source

Commercially available Weikangling Capsules

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

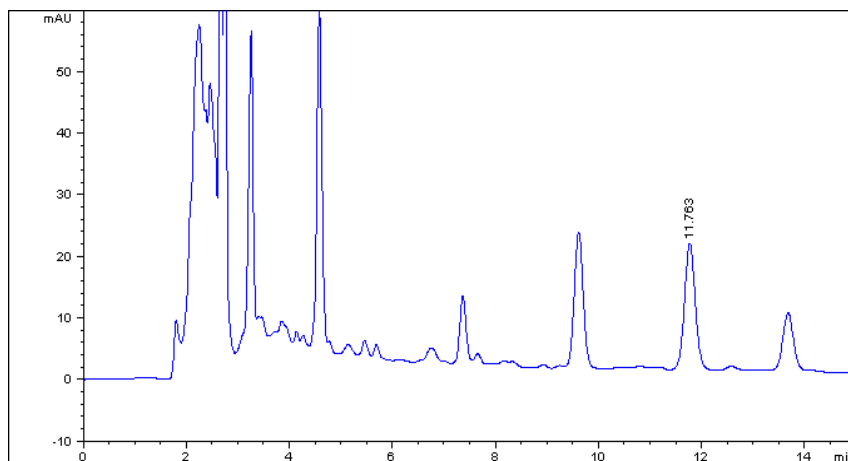
Accurately weigh 0.3 g of the contents in a stoppered conical flask, accurately add 25 mL of dilute ethanol TS, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with dilute ethanol TS and mix well. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.2 mol/L ammonium acetate- glacial acetic acid (15:85)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	3.705	11.763	20.46	298.7	15523	1.03

# Weishuning Granules (*Weishuning Keli*) – 胃舒宁颗粒

## Sample source

Commercially available Weishuning Granules

## Chemical reference substances

ammonium glycyrrhizinate (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0731-9704)

## Preparation of test solution

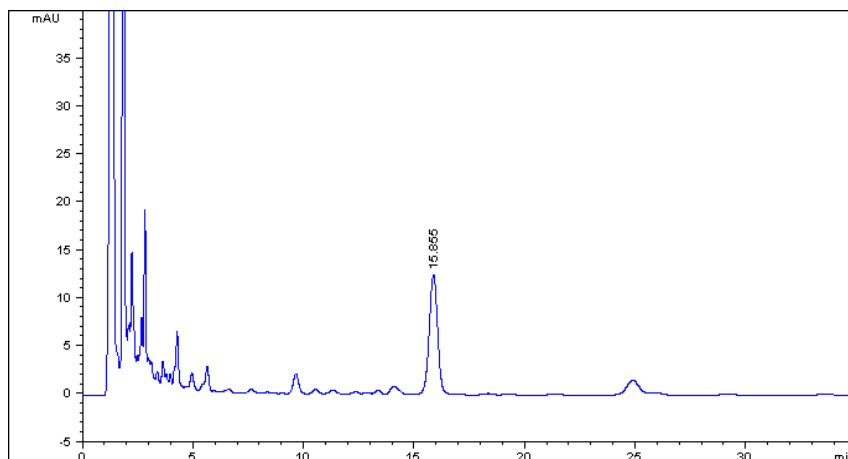
Grind a quantity of granules to a fine powder and mix thoroughly, accurately weigh 0.3 g in a stoppered conical flask, accurately add 25 mL of a mixture of methanol and 0.017 mol/L solution of phosphoric acid (65:35), stopper tightly and weigh, allow to soak for 1 hour, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost the weight with the above mixture and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.2 % phosphoric acid (33:67)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Glycyrrhizic acid	9.57	15.855	12.47	325.0	8793	0.99

# Wuji Baifeng Pills (*Wuji Baifeng Wan*) – 乌鸡白凤丸

## Sample source

Commercially available Wuji Baifeng Pills

## Chemical reference substances

paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

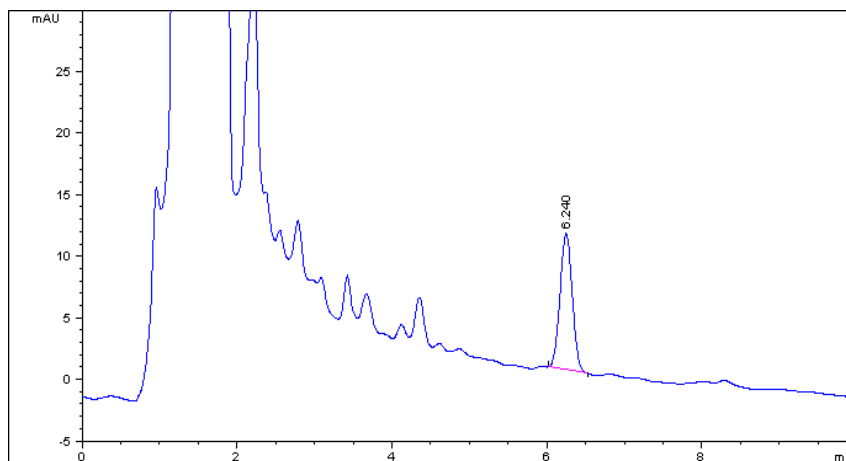
Grind the pills to a fine powder, accurately weigh 2 g, accurately add 10 mL of 30 % ethanol, weigh, shake at intervals, allow to stand for 24 hours, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 30 % ethanol, mix well and filter. Accurately measure 5 mL of the filtrate, apply to the column (1.5 cm in internal diameter; 12 cm in height) packed with D 101 macroporous adsorptive resins. Elute with 100 mL of 30 % ethanol, collect the eluent, evaporate to dryness, dissolve the residue in several 5 mL portions of water, transfer to a 25 mL volumetric flask, wash the containers with methanol several times in the same volumetric flask, dilute with methanol to volume and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: methanol-water (30:70)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	4.200	6.240	11.11	122.2	7476	0.97

# Chinese Gall (*Galla Chinensis*) – 五倍子

## Sample source

Commercially available Chinese Gall (Beijing)

## Chemical reference substances

Gallic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0831-9501)

## Preparation of test solution

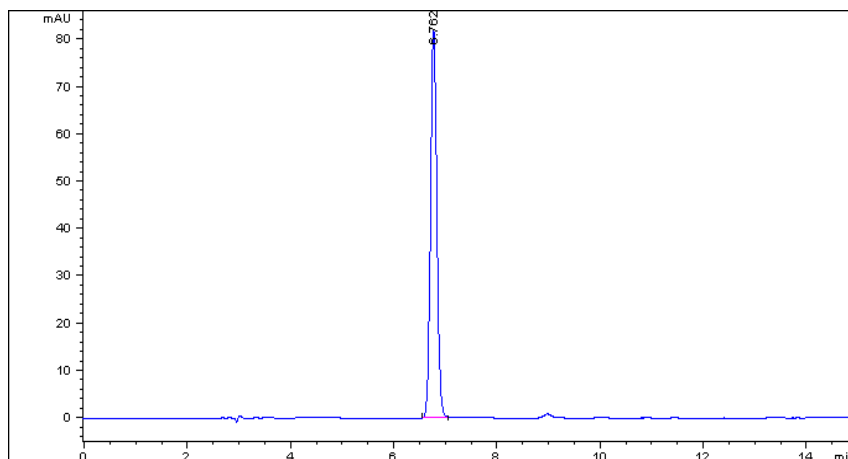
Accurately weigh 0.5 g of the fine powder, accurately add 50 mL of 4 mol/L hydrochloric acid, heat on a water bath for 3.5 hours, allow to cool, filter, accurately measure 1 mL of the filtrate in a 100 mL volumetric flask, dilute with 50 % methanol to volume, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB-Aq C18 4.6×150 mm, 5 µm (880975-914)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1 % phosphoric acid (15:85)
- Detector wavelength: 273 nm
- Flow rate: 1.0 mL/min
- Injection volume: 2 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Diode-array detector (G1315B)
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Gallic acid	1.705	6.762	81.93	697.8	15381	1.08

# American Ginseng (*Radix Panacis Quinquefolii*) – 西洋参

## Sample source

Commercially available American Ginseng

## Chemical reference substances

1. Ginsenoside Rb1, 2. Ginsenoside Rg1, 3. Ginsenoside Re (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 2. 110703-200322 3. 0754-9912)

## Preparation of test solution

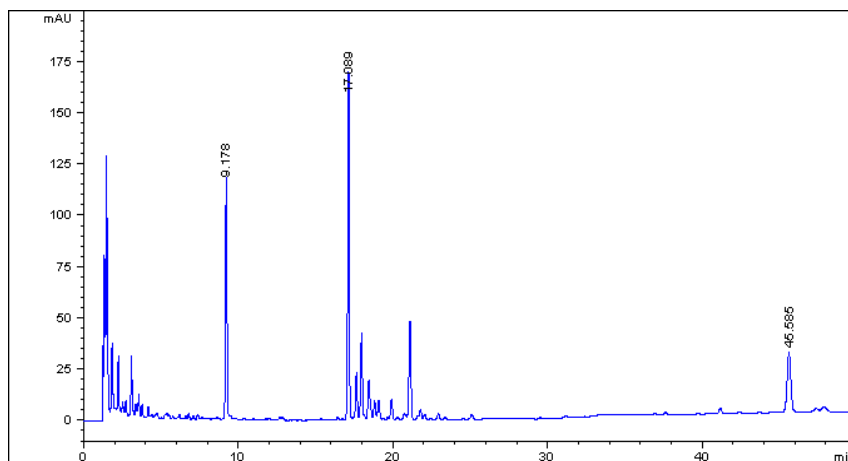
Accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 50 mL of n-butanol saturated with water and weigh. Heat under reflux on a water bath for 1.5 hours, allow to cool and weigh again, replenish the lost solvent with n-butanol saturated with water, mix well and filter. Evaporate accurately 25 mL of the filtrate to dryness in an evaporating dish, dissolve the residue in 50 % methanol, transfer to a 10 mL volumetric flask, dilute with 50 % methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 40 °C
- Mobile phase: A: 0.1 % phosphoric acid, B: acetonitrile; 0-15 min, 19-20 %; 15-30 min, 20-35 %; 30-35 min, 35-55 %; 35-45 min, 55-60 %
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Inject volume: 3 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
ginsenoside Rg1	5.118	9.178	115.45	780.2	46664	1.03
ginsenoside Rb1	10.393	17.089	156.97	1174.6	132102	0.93
ginsenoside Re	29.390	45.585	29.06	477.0	184195	1.01

# Common Self-heal Fruit-Spike (*Spica Prunellae*) – 夏枯草

## Sample source

Commercially available Common Selfheal Fruit-Spike

## Chemical reference substances

Ursolic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 10742-200212)

## Preparation of test solution

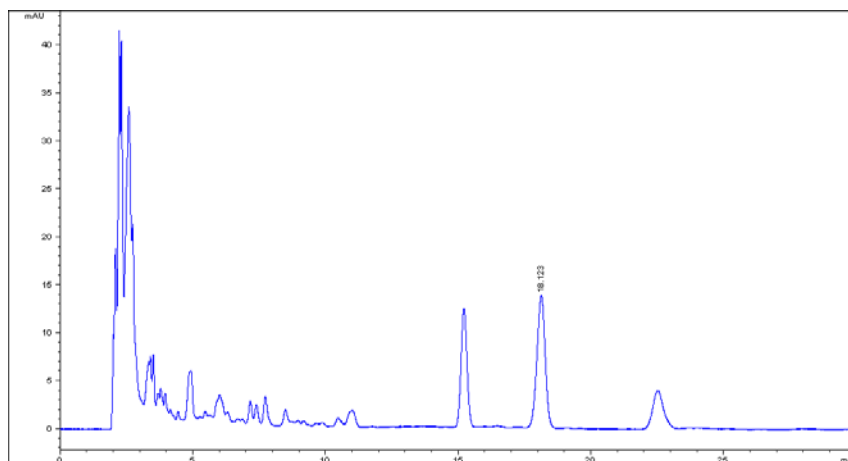
Accurately weigh 2 g of the powder in a Soxhlet extractor, add a quantity of ether and soak overnight, heat under reflux for 6 hours, evaporate the solvent. Dissolve the residue in anhydrous ethanol, transfer to a 10 mL volumetric flask, and dilute to volume with anhydrous ethanol. Measure accurately 1 mL to a 10 mL volumetric flask, dilute with anhydrous ethanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 50 °C
- Mobile phase: acetonitrile-1.4 % phosphoric acid (72:28)
- Detector wavelength: 210 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ursolic acid	6.249	18.123	13.77	298.4	16225	0.95



# Xiatianwu Tablets (*Xiatianwu Pian*) – 夏天无片

## Sample source

Commercially available Xiatianwu Tablets

## Chemical reference substances

Protopine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110853-200201)

## Preparation of test solution

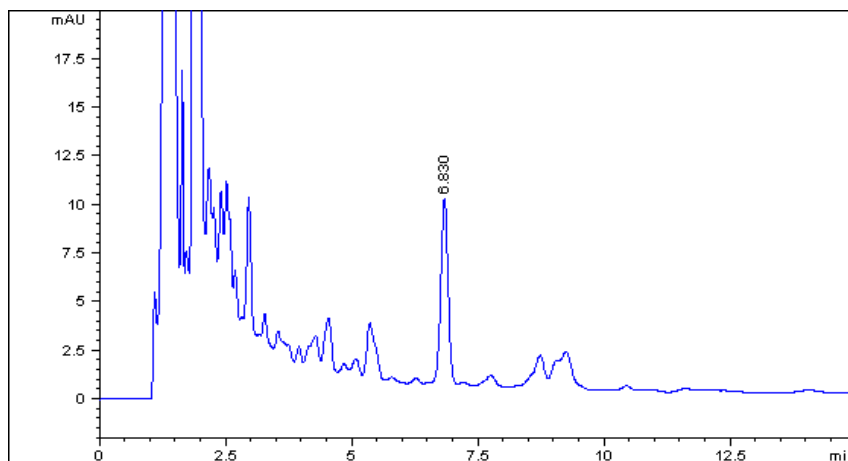
Remove the coatings of 10 tablets and grind to a fine powder, accurately weigh 0.6 g in a stoppered conical flask, accurately add 50 mL of 50 % methanol, and weigh. Heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with 50 % methanol, and mix well. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (containing 3 % glacial acetic acid and 0.8 % triethylamine) (21:79)
- Detector wavelength: 289nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Protopine	3.553	6.830	9.52	95.1	11233	0.97

# Decumbent Corydalis Rhizome (*Rhizoma Corydalis Decumbentis*)

仙茅

## Sample source

Commercially available Decumbent Corydalis Rhizome

## Chemical reference substances

Curculigoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110771-200203)

## Preparation of test solution

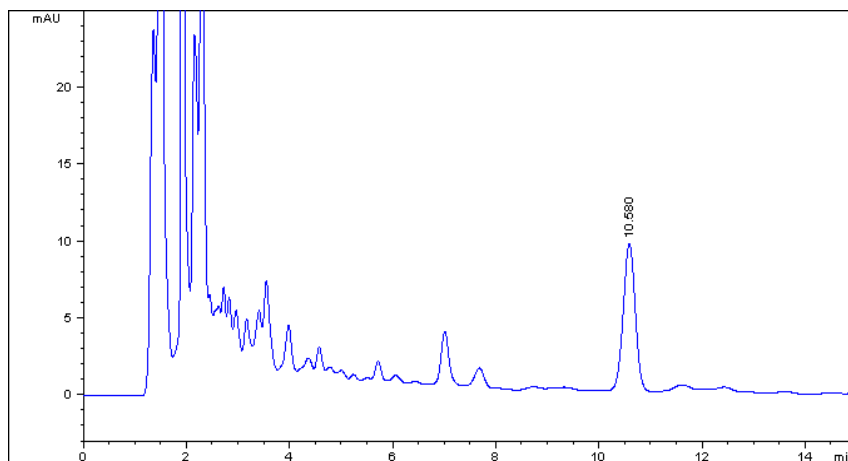
Accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol and weigh. Heat under reflux for 2 hours, allow to cool, and weigh again, replenish the lost weight with methanol, mix well and filter. Evaporate accurately 20 mL of the filtrate to dryness, dissolve the residue in methanol, transfer to a 10 mL volumetric flask, dilute with methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (20:80)
- Detector wavelength: 285 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Curculigoside	7.817	10.580	9.57	154.0	9927	0.98

# Xiangsha Liujun Pills (*Xiangsha Liujun Wan*) – 香砂六君丸

## Sample source

Commercially available Xiangsha Liujun Pills

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110721-200211)

## Preparation of test solution

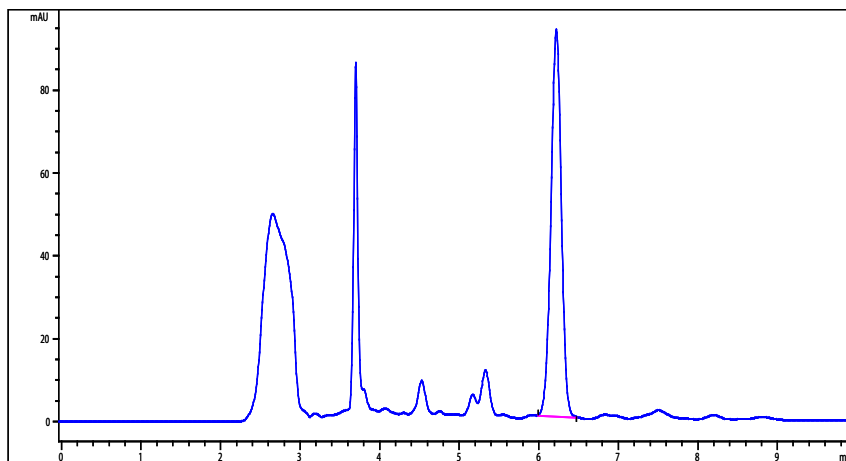
Accurately weigh 10 g of the pills, grind to a fine powder, accurately weigh 0.25 g in a 25 mL volumetric flask, add a quantity of methanol, allow to stand for 2 hours, treat ultrasonically for 1 hour, allow to cool, dilute with methanol to volume, shake well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.2% phosphoric acid (26:74)
- Detector wavelength: 284 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Hesperidin	0.991	6.221	93.50	847.5	11202	0.96

# Xiangsha Yangwei Pills (*Xiangsha Yangwei Wan*) – 香砂养胃丸

## Sample source

Commercially available Xiangsha Yangwei Pills

## Chemical reference substances

1. Magnolol, 2. Honokiol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1.0729-200308, 2.730-9204)

## Preparation of test solution

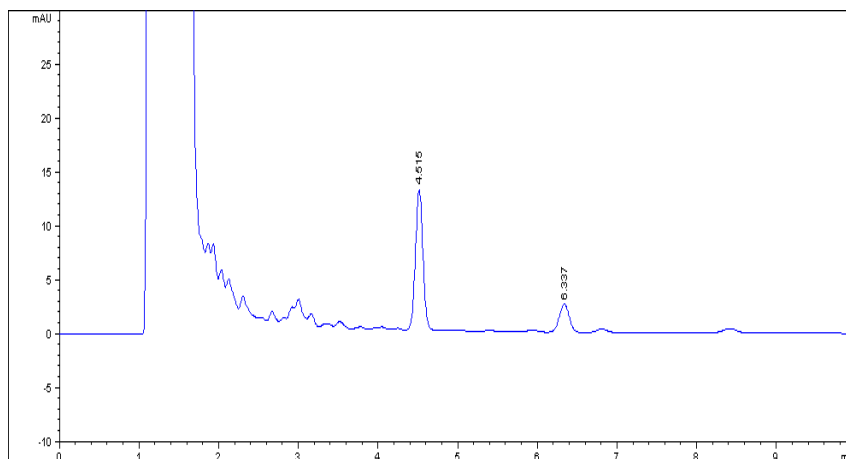
Grind a quantity of the pills to a fine powder, accurately weigh 2.5 g of the powder in a Soxhlet extractor, heat under reflux with a quantity of methanol for 3 hours and evaporate the extract to dryness. Dissolve the residue in methanol, transfer to a 25 mL volumetric flask, dilute with methanol to volume. Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid (60:38:2)
- Detector wavelength: 294 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Magnolol	2.762	4.515	13.02	85.2	11293	1.03
Honokiol	4.281	6.337	2.58	22.1	12513	0.99

# Xiangsha Zhizhu Pills (*Xiangsha Zhizhu Wan*) – 香砂枳术丸

## Sample source

Commercially available Xiangsha Zhizhu Pills

## Chemical reference substances

Hesperidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110721-200211)

## Preparation of test solution

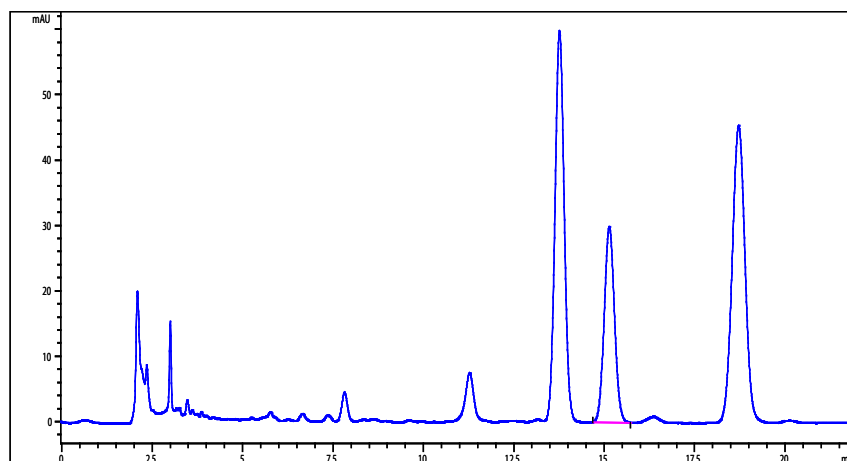
Grind a quantity of the pills to a fine powder, accurately weigh 0.3 g, accurately add 50 mL of methanol, heat under reflux on a water bath for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, mix well, filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 20 °C
- Mobile phase: acetonitrile-0.3 % phosphoric acid (20:80)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Hesperidin	5.056	15.14	29.96	594.8	13803	1.04

# Dahurian Rhododendron Syrup (*Syrups Rhododendri Daurici*)

## 消咳喘糖浆

### Sample source

Commercially available Dahurian Rhododendron Syrup

### Chemical reference substances

Farrerol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110850-200203)

### Preparation of test solution

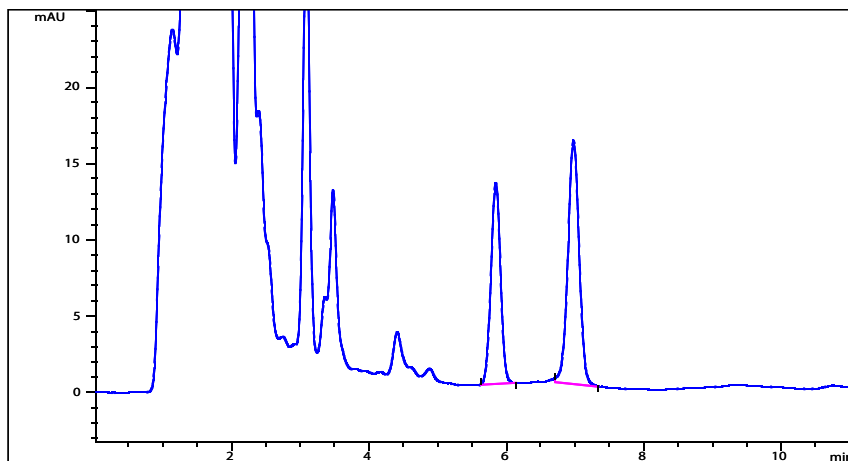
Accurately measure 1.0 mL of the syrup in a 10 mL volumetric flask, dilute with methanol to volume, mix well, filter and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (60:40)
- Detector wavelength: 295 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Farrerol	4.815	6.978	15.94	181.6	9002	0.96

# Xiaomi Suppositories (*Xiaomi Shuan*) – 消糜栓

## Sample source

Commercially available Xiaomi Suppositories

## Chemical reference substances

Ginsenoside Re (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0754-9912)

## Preparation of test solution

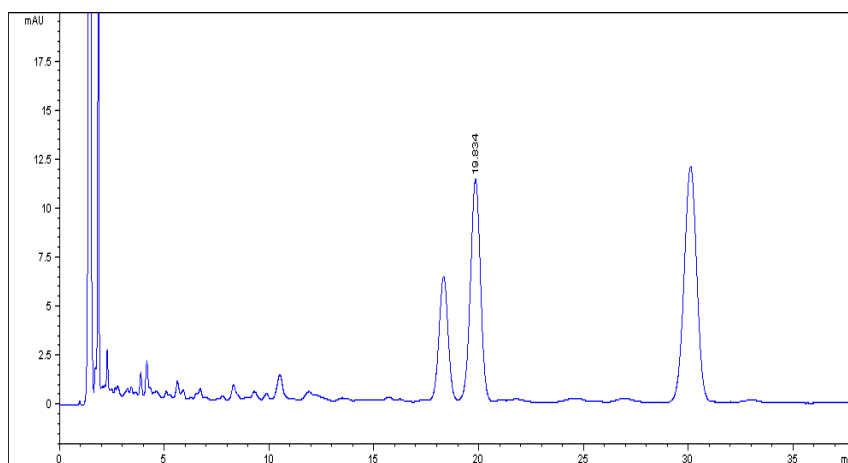
Cut the suppositories into pieces. Accurately weight 3.0 g of the pieces in a stoppered conical flask. Accurately add 50 mL of n-butanol saturated with water and weigh. Heat under reflux for 1 hour, allow to cool. Weigh again and replenish the lost weight with above solution, mix well and filter. Accurately measure 25 mL of the filtrate in a separator funnel, wash with two 25 ml quantities of ammonia TS saturated with n-butanol and then wash with 25 ml of water saturated with n-butanol. Evaporate the n-butanol extract to dryness, dissolve the residue in an appropriate amount of methanol, and transfer to a 5 mL volumetric flask. Dilute with methanol to volume, mix well, allow to stand for 15 minutes below 0 °C, filter immediately. Use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.05 % phosphoric acid (20:80)
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ginsenoside Re		19.834	11.31	372.5	8392	0.98

# Xiaoshuan Tongluo Capsules (*Xiaoshuan Tongluo Jiaonang*)

## 消栓通络胶囊

### Sample source

Commercially available Xiaoshuan Tongluo Capsules

### Chemical reference substances

Ginsenoside Rg1 (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110703-200322)

### Preparation of test solution

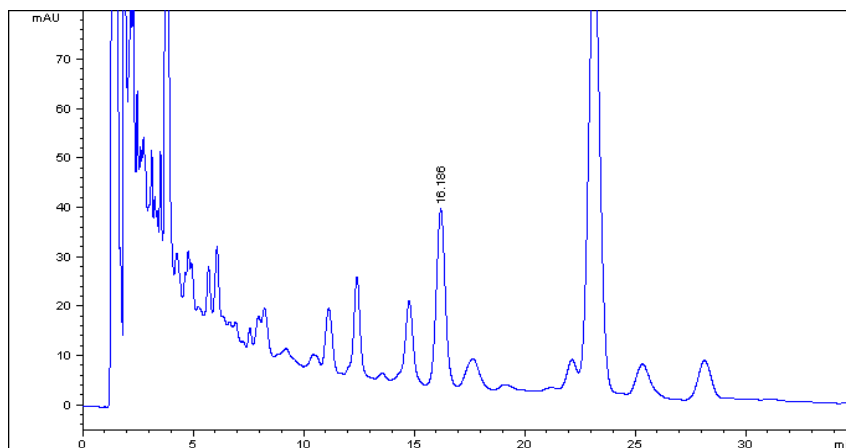
Grind the contents of the capsules to a fine powder. Accurately weigh 2 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol, weigh, heat under reflux for 2 hours, allow to cool and weigh again. Replenish the lost weight with methanol, mix well, and filter. Accurately measure 25 mL of the filtrate and evaporate to dryness. Dissolve the residue in 30 mL of water, extract with two 20 mL quantities of ether, discard the ether extract, extract with four 20 mL quantities of n-butanol saturated with water, combine the n-butanol extracts, wash with two 30 mL quantities of ammonia TS, and wash with two 20 mL quantities of water saturated with n-butanol. Evaporate n-butanol to dryness, dissolve the residue with methanol in a 10 mL volumetric flask, dilute with methanol to volume, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX XDB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (993967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.05 % phosphoric acid (20.5:79.5)
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ginsenoside Rg1		16.186	35.84	995.1	8141	1.03



# Xiaoshuan Tongluo Tablets (*Xiaoshuang Tongluo Pian*)

## 消栓通络片

### Sample source

Commercially available Xiaoshuan Tongluo Tablets

### Chemical reference substances

Ginsenoside Rg1 (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110703-200322)

### Preparation of test solution

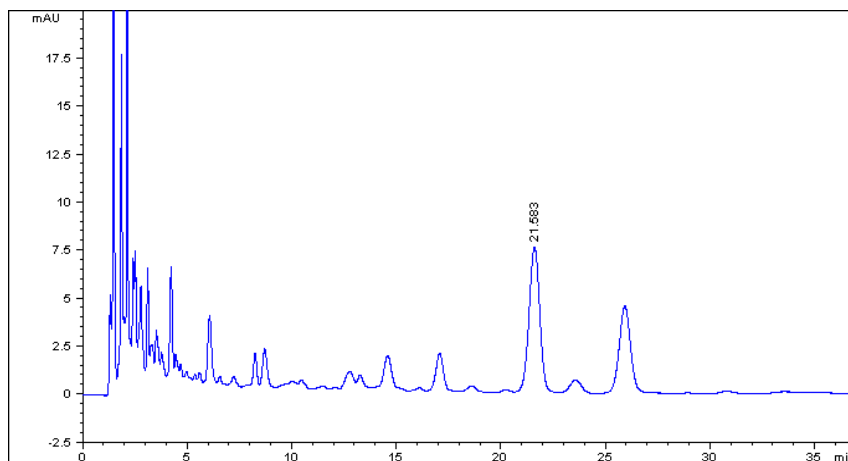
Remove the coatings from 20 tablets and grind to a fine powder, accurately weigh 2 g of the powder, accurately add 50 mL of methanol, weigh, heat under reflux for 3 hours, allow to cool, weigh again, replenish the lost weight, mix well, and filter. Accurately measure 25 mL of the filtrate, evaporate to dryness, dissolve the residue in 20 mL of water in a separator, extract with 30, 30, 20 and 20 ml quantities of n-butanol saturated with water by shaking, combine the n-butanol extracts. Wash twice each with 25 mL of 1 % solution of sodium hydroxide, then wash with two 25 ml quantities of water saturated with n-butanol, evaporate the n-butanol extracts to dryness, dissolve the residue in methanol in a 25 mL volumetric flask, dilute with methanol to volume, mix well, filter through a millipore membrane (0.45  $\mu\text{m}$ ), and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX XDB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (993967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.05 % phosphoric acid (20:80)
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ginsenoside Rg1		21.583	7.54	264.2	8892	0.98

# Xiaoyin Tablets (*Xiaoyin Pian*) – 消银片

## Sample source

Commercially available Xiaoyin Tablets

## Chemical reference substances

Matrine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110805-200306)

## Preparation of test solution

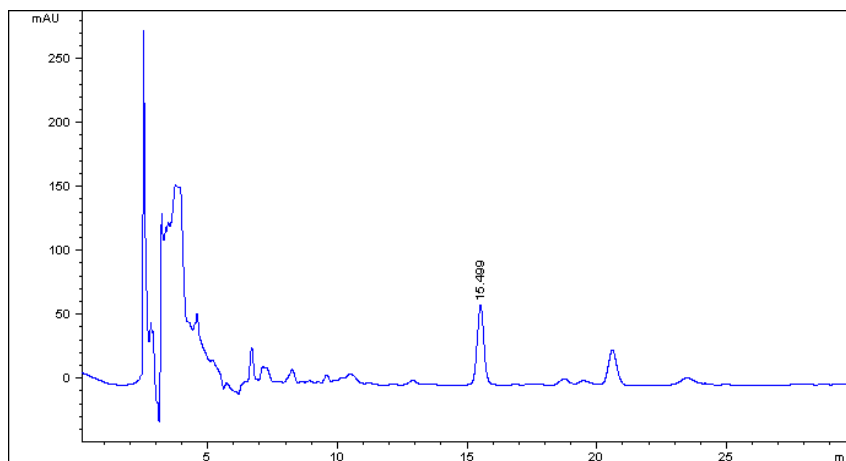
Accurately weigh 30 tablets, remove the coatings and grind to a fine powder, accurately weigh 3.5 g in a stoppered conical flask, add 1 mL of concentrated ammonia TS and 30 mL of chloroform, stopper tightly, shake thoroughly and allow to stand overnight. Filter, wash the flask and residue three times with 15 mL of chloroform. Combine the filtrate and washings, evaporate to dryness. Dissolve the residue in methanol. Transfer to a 25 mL volumetric flask, dilute to volume and mix well. Filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX Bonus-RP, 4.6×250 mm, 5 µm (880668-901)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (85:15) (pH 7.5)
- Detector wavelength: 220 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Matrine	5.200	15.499	61.93	1115.2	17390	1.02

# Xiaochaihu Granules (*Xiaochaihu Keli*) – 小柴胡颗粒

## Sample source

Commercially available Xiaochaihu Granules

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

## Preparation of test solution

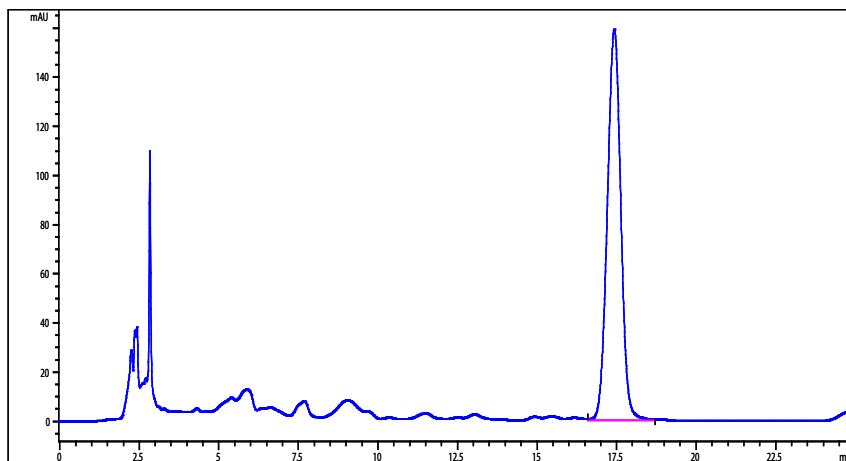
Grind the granules to a fine powder. Accurately weigh 0.6 g of the powder in a 10 mL volumetric flask, accurately add 7 mL of ethanol. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 70 % ethanol, mix well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-0.36 % phosphoric acid (44:56)
- Detector wavelength: 315 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Baicalin	5.972	17.43	159.09	4685.1	8311	0.998

# Xiaochaihu Tablets (*Xiaochaihu Pian*) – 小柴胡片

## Sample source

Commercially available Xiaochaihu Tablets

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

## Preparation of test solution

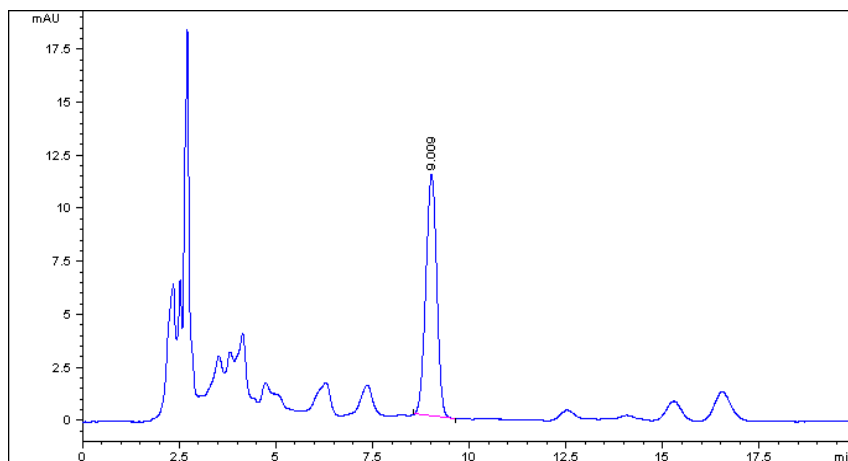
Grind 20 tablets to a fine powder, accurately weigh 0.3 g in a 100 mL volumetric flask, add 70 mL of 70 % ethanol and treat ultrasonically for 30 minutes, allow to cool, add 70 % ethanol to volume, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 20 °C
- Mobile phase: methanol-4 % glacial acetic acid (48:52)
- Detector wavelength: 315 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	2.603	9.009	11.39	224.5	4809	0.95

# Xiao'er Baibu Zhike Syrup (*Xiao'er Baibu Zhike Tangjiang*)

## 小儿百部止咳糖浆

### Sample source

Commercially available Xiao'er Baibu Zhike Syrup

### Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

### Preparation of test solution

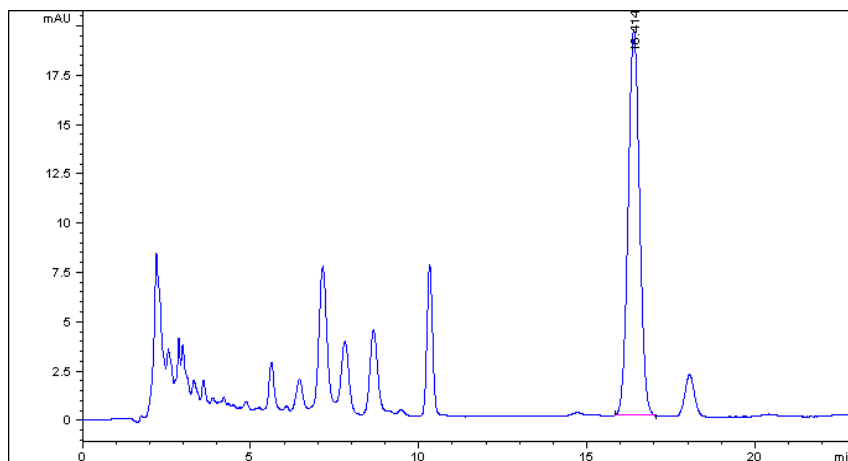
Accurately measure 2.0 mL of the syrup to a 100 mL volumetric flask, dissolve and dilute to volume with water, mix well. Accurately measure 10 mL to a 50 mL volumetric flask, dilute to volume with 65 % methanol and mix well, filter, and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.2 % phosphoric acid (45:55)
- Detector wavelength: 276nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	5.566	16.414	19.56	463.0	11102	1.03

# Xiao'er Huashi Pills (*Xiao'er Huashi Wan*) – 小儿化食丸

## Sample source

Commercially available Xiao'er Huashi Pills

## Chemical reference substances

emodin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110756-200210)

## Preparation of test solution

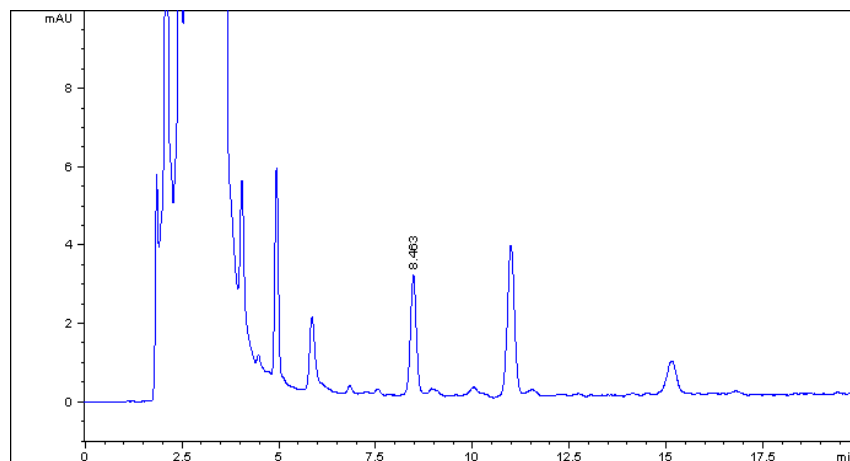
Cut the pills into pieces, accurately weigh 6 g, mix well with an equal quantity of kieselguhr, accurately weigh 2 g to a conical flask, accurately add 25 mL methanol, weigh, heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, mix well, and filter. Accurately measure 10 mL of the filtrate to a round-bottomed flask, evaporate the methanol on a water bath, add 20 mL of a solution of 2.5 mol/L sulfuric acid, treat ultrasonically for 10 minutes to dissolve, heat on a water bath for 1 hour, cool immediately, extract with four 25 mL quantities of ether, combine the ether extracts, wash with 15 mL of water, discard the washings, evaporate the ether on low temperature to dryness, dissolve the residue in a quantity of methanol in a 25 mL volumetric flask, dilute with methanol to volume, and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: Hypersil ODS, 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (7991618-584)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: methanol-0.05 % phosphoric acid (80:20)
- Detector wavelength: 289 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Emodin	2.385	8.463	3.05	31.7	15498	1.02

# Xiao'er Kechuan Granules (*Xiao'er Kechuan Keli*) – 小儿咳喘颗粒

## Sample source

Commercially available Xiao'er Kechuan Granules

## Chemical reference substances

ephedrin hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

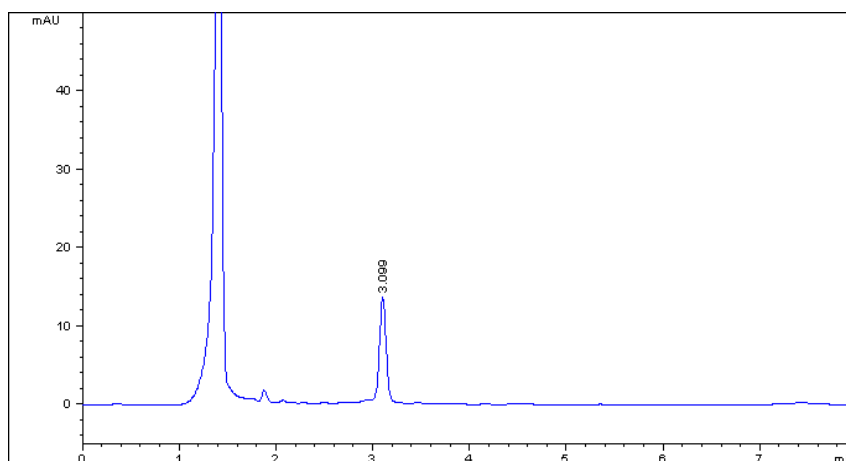
Grind 1 package of the granules to a fine powder, accurately weigh 2.0 g, add 120 mL of 5 mol/L sodium hydroxide and shake well. Add 7.5 g of sodium chloride, treat ultrasonically for 10 minutes, distill, transfer 95 mL of the distillate to a 100 mL volumetric flask, containing 5 mL of 0.5 mol/L hydrochloric acid, add water to volume, and shake well. Accurately transfer 10 mL to a 25 mL volumetric flask, add 1 mL of periodic acid (0.25 g in 10mL) and 2.5 mL of 0.25 mol/L sodium hydroxide, shake well, allow to stand for 30 minutes, adjust to pH 7 with 0.5 mol/L hydrochloric acid, add methanol to volume, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (58:42)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Ephedrin	1.582	3.099	13.27	62.6	10264	1.01

# Xiao'er Qingre Tablets (*Xiao'er Qingre Pian*) – 小儿清热片

## Sample source

Commercially available Xiao'er Qingre Tablets

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110749-200309)

## Preparation of test solution

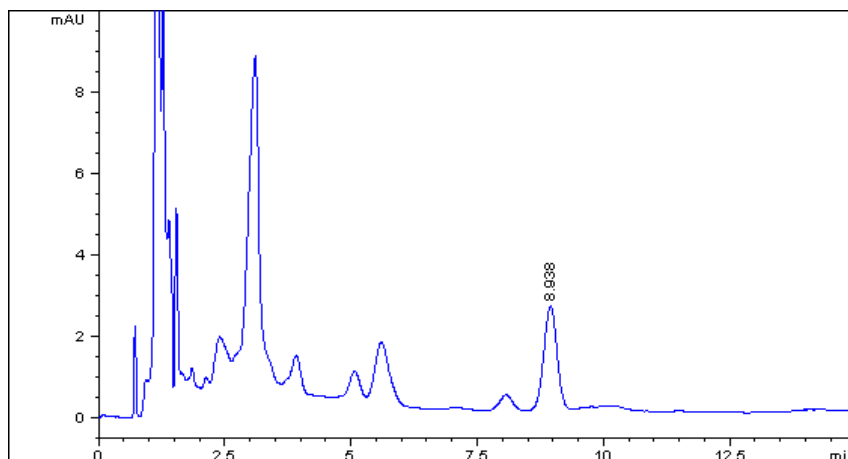
Remove the coatings from 20 tablets and grind to a fine powder, accurately weigh 0.5 g of the powder, accurately add 50 mL of methanol, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well, and filter. Accurately measure 10 mL of the filtrate in a 25 mL volumetric flask, dilute with methanol to volume, and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (25:75)
- Detector wavelength: 238 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Geniposide	4.959	8.938	2.54	45.8	5513	0.99



# Xiao'er Qingre Zhike Mixture (*Xiao'er Qingre Zhike Koufuye*)

## 小儿清热止咳口服液

### Sample source

Commercially available Xiao'er Qingre Zhike Mixture

### Chemical reference substances

Ephedrine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products)

### Preparation of test solution

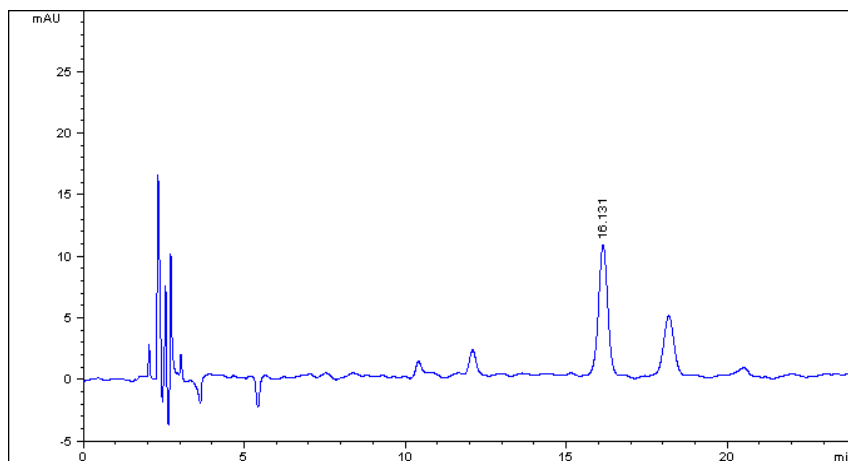
Accurately measure 5 mL, add 10 mL of water and 0.5 mL of concentrated ammonia TS, extract with 30, 30, 20, 20 and 20 mL quantities of ether, combine the ether extracts, add 2 mL of a mixture of hydrochloric acid and ethanol (1:20), mix well, evaporate the solvents to dryness at low temperature, dissolve the residue in 5 mL of ethanol in a 25 mL volumetric flask, dilute with 0.1 mol/L solution of hydrochloric acid to volume, and mix well.

### Chromatographic conditions

- Column: Reprosil Pur C18 4.0×250 mm, 5 μm
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (containing 0.1 % triethylamine) (4:96)
- Detector wavelength: 275 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ephedrine	7.065	16.131	10.56	208.2	15666	0.98

# Xiaojianzhong Granules (*Xiaojianzhong Keli*) – 小建中颗粒

## Sample source

Commercially available Xiaojianzhong Granules

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

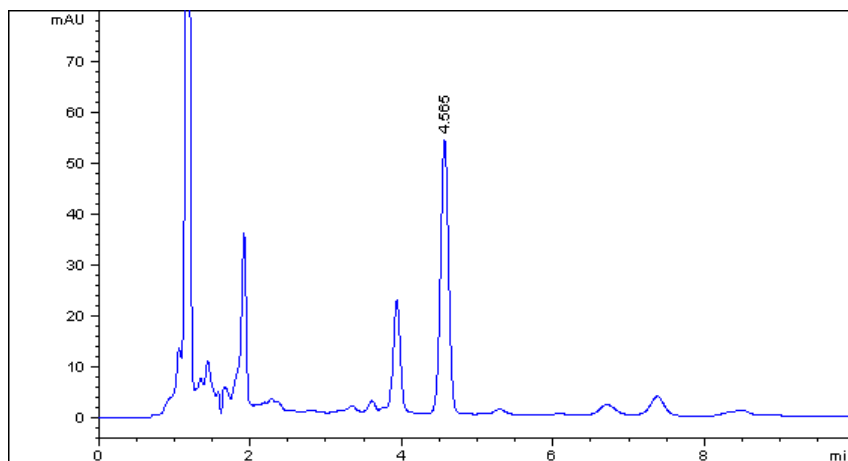
Grind the granules to a fine powder, accurately weigh about 0.25 g of the powder in a stoppered conical flask, accurately add 25 mL of dilute ethanol TS, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, and replenish the lost weight with dilute ethanol TS. Mix well, allow to stand, filter the supernatant, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (17:83)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Paeoniflorin	2.043	4.565	53.91	400.2	8987	1.00

# Xiaoqinglong Mixture (*Xiaoqinglong Heji*) – 小青龙合剂

## Sample source

Commercially available Xiaoqinglong Mixture

## Chemical reference substances

Paeoflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

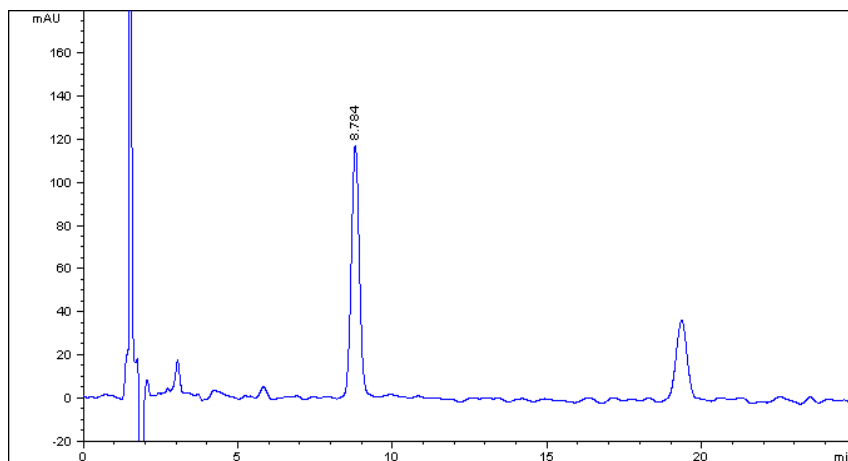
Shake the mixture well, accurately measure 3 mL of the mixture in a 25 mL volumetric flask, dilute with methanol to volume, mix well, and filter.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-2 % acetic acid (containing 0.1 % isopropanol) (25:75)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 2 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	6.320	8.784	116.44	2068.5	5685	1.03

# Xiaoqinglong Granules (*Xiaoqinglong Keli*) – 小青龙颗粒

## Sample source

Commercially available Xiaoqinglong Granules

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

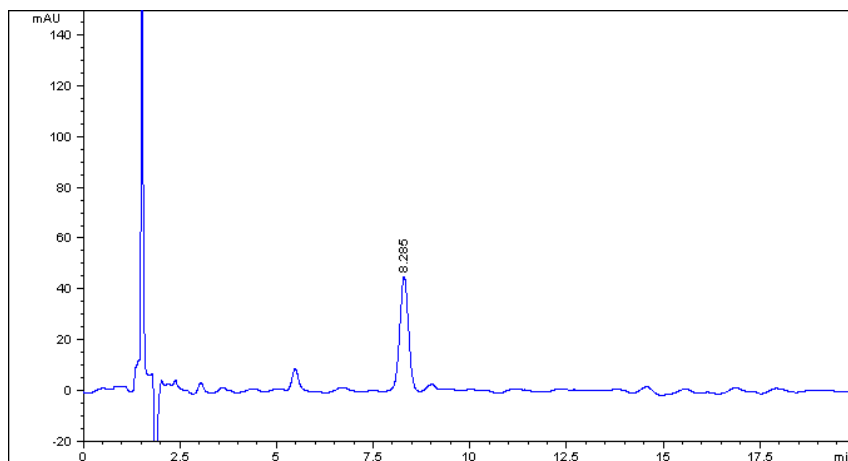
Grind the granules to fine a powder, accurately weigh 0.5 g of the powder in a 25 mL volumetric flask, add a quantity of methanol, treat ultrasonically for 30 minutes, allow to cool, dilute with methanol to volume, mix well, and filter.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-2 % acetic acid (containing 0.1 % isopropanol) (27:73)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeoniflorin	5.904	8.285	44.83	700.0	6589	1.00

# Xinqin Granules (*Xinqin Keli*) – 辛芩颗粒

## Sample source

Commercially available Xinqin Granules

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

## Preparation of test solution

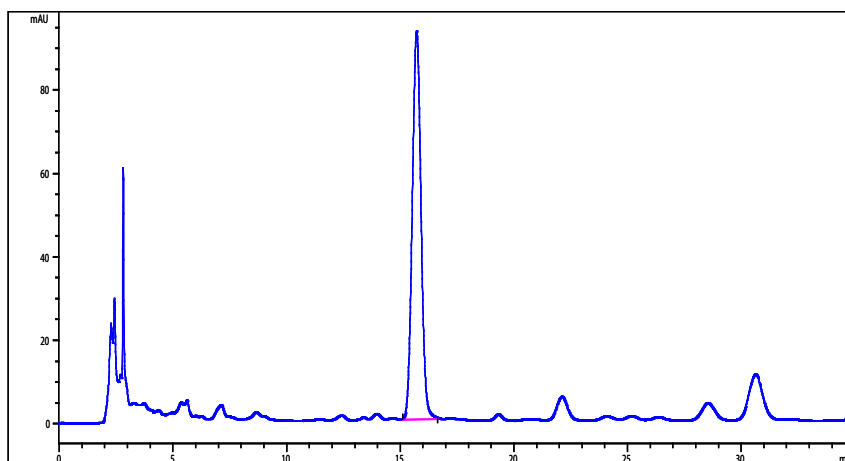
Grind the granules to fine a powder, accurately weigh 0.3 g of the powder in a stoppered conical flask, accurately add 50 mL of 70 % ethanol, stopper tightly, weigh, treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 70 % ethanol and mix thoroughly. Filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-0.36 % phosphoric acid (45:55)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Baicalin	5.29	15.725	93.06	2488.0	8149	1.05

# Xinqingning Tablets (*Tabellae Rhei Preparata*) – 新清宁片

## Sample source

Commercially available Xinqingning Tablets

## Chemical reference substances

1. Chrysophanol, 2. Emodin  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1.0796-200309, 2. 0756-200210)

## Preparation of test solution

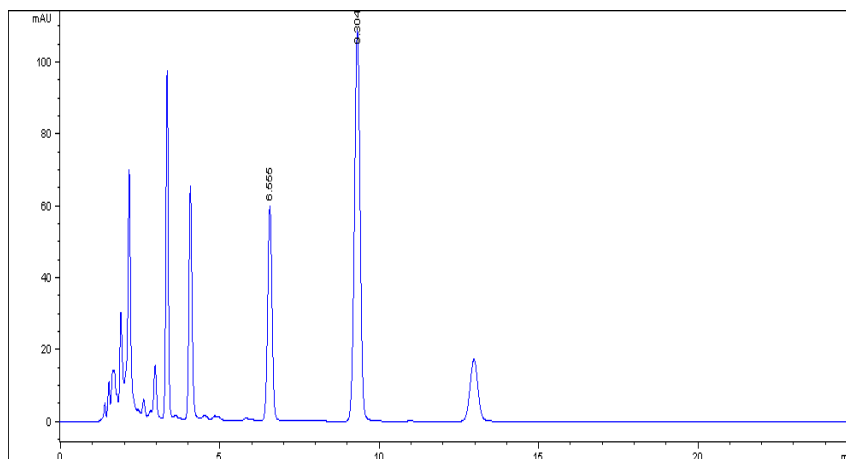
Accurately weight 20 tablets, remove the coatings and grind to a fine powder. Accurately weigh 0.1 g of the powder in a stoppered conical flask, accurately add 50 mL of methanol, stopper tightly and weigh. Heat under reflux for 1.5 hours, cool, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 25 mL of the filtrate, evaporate the filtrate to dryness, dissolve the residue in 27 mL of hydrochloric acid solution (2:27), add 20 mL of chloroform, heat under reflux for 30 minutes, cool immediately, transfer to a separating funnel, wash the container with a quantity of chloroform, combine the washings in the separating funnel, separate the chloroform layer, extract the water solution with one 15 mL and two 10 mL quantities of chloroform, combine the chloroform extracts, add a quantity of anhydrous sodium sulfate. Evaporate the chloroform extracts to dryness, dissolve the residue in 2 mL of ethyl acetate, and transfer to a 10 mL volumetric flask, add methanol to volume, mix well, and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-methanol-0.1 % phosphoric acid (35:37:28)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Emodin	4.462	6.555	59.70	561.8	11585	1.00
Chrysophanol	6.753	9.304	108.71	1331.5	13762	0.98

# Xintong Mixture (*Xintong Koufuye*) – 心通口服液

## Sample source

Commercially available Xintong Mixture

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110752-200209)

## Preparation of test solution

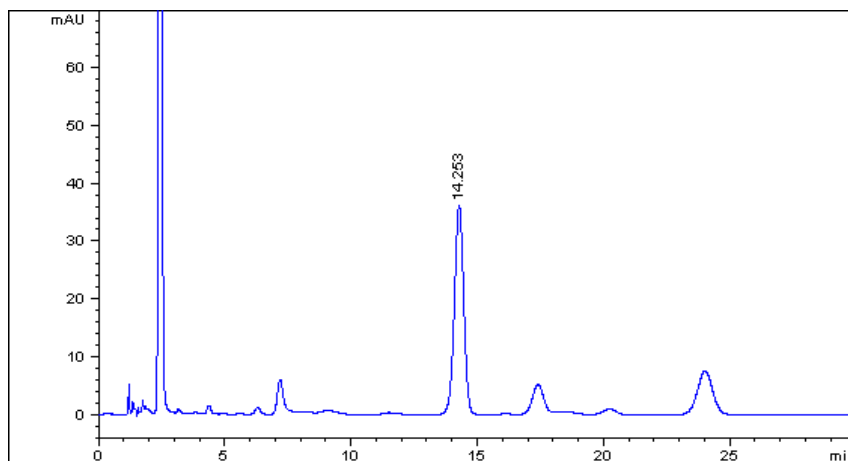
Accurately measure 5 mL of the mixture, transfer to a 50 mL volumetric flask, dilute with acetone to volume and mix well. Centrifuge, accurately measure 5 mL of the supernatant liquid, transfer to a 50 mL volumetric flask, dilute with 30 % methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (21:79)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	8.502	14.253	36.15	928.8	7274	0.97

# Xuhan Weitong Granules (*Xuhan Weitong Keli*) – 虚寒胃痛颗粒

## Sample source

Commercially available Xuhan Weitong Granules

## Chemical reference substances

Paeoniflorin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110736-200220)

## Preparation of test solution

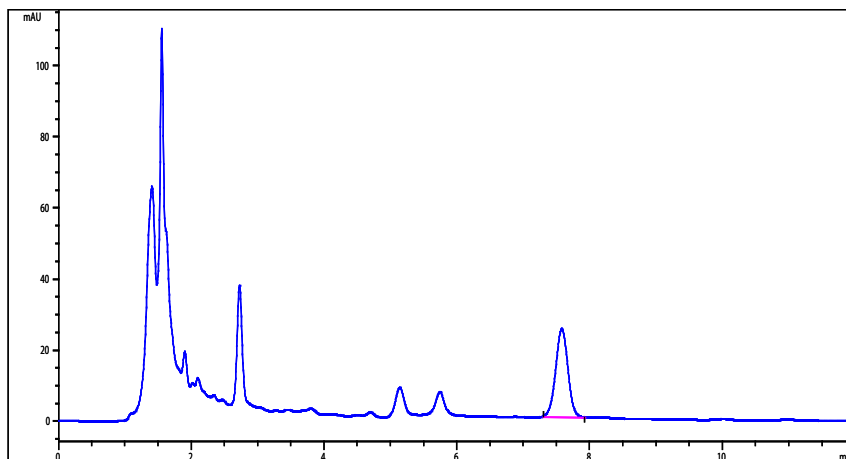
Grind a quantity of granules to a fine powder. Accurately weigh 0.1 g of the powder in a 10 mL volumetric flask and add 8 mL of water. Treat ultrasonically for 30 minutes, allow to cool, dilute with water to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-0.02 %/L potassium dihydrogen phosphate (28:72)
- Detector wavelength: 230 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Paeoniflorin	5.320	7.584	24.87	320.8	8248	0.97



# Paniculate Swallowwort Root

(*Radix et Rhizoma Cynanchi Paniculati*) – 徐长卿

## Sample source

Commercially available Paniculate Swallowwort Root (Jiangsu province)

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110822-200205)

## Preparation of test solution

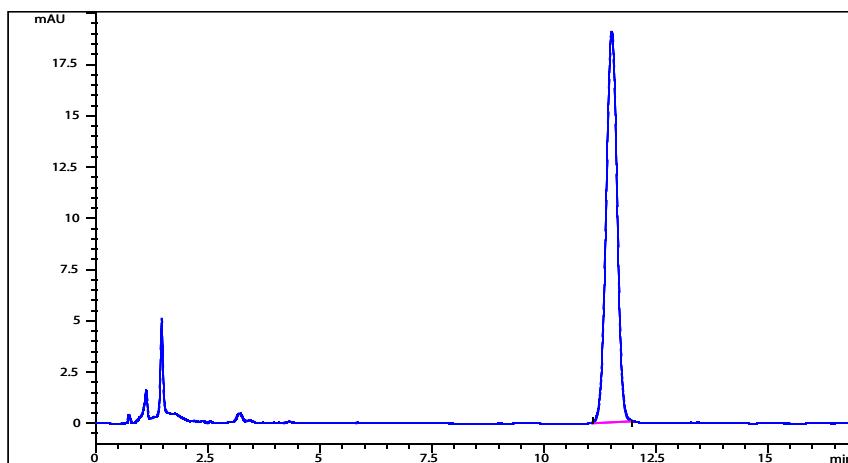
Accurately weigh 0.5 g of the powder in a 100 mL stoppered conical flask, accurately add 50 mL of methanol and weigh. Treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost solvent with methanol, mix well and filter. Accurately measure 1 mL of the filtrate in a 10 mL volumetric flask, dilute with methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (45:55)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	8.601	11.522	19.06	324.4	10512	0.99

# Himalayan Teasel Root (*Radix Dipsaci*) – 续断

## Sample source

Commercially available Himalayan Teasel Root

## Chemical reference substances

Asperosaponin IV (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 111685-200401)

## Preparation of test solution

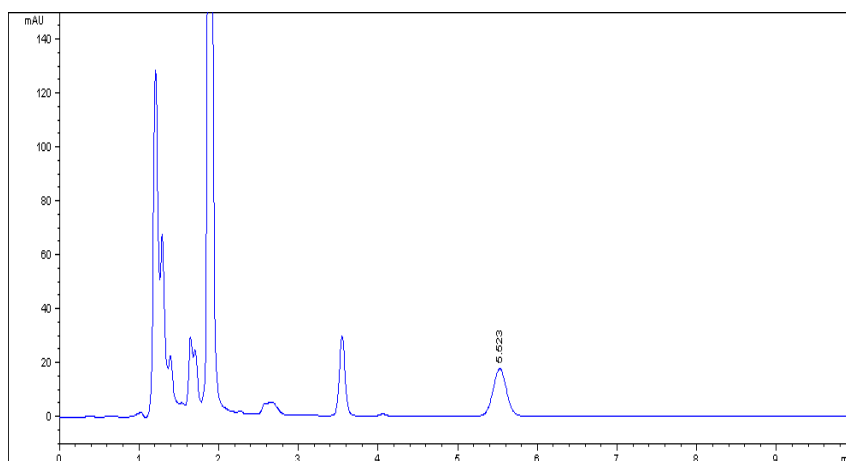
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool and weigh again, replenish the lost solvent with methanol, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with the mobile phase to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (30:70)
- Detector wavelength: 212 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
asperosaponin IV	2.682	5.523	17.60	204.5	5337	1.02

# Xueshuan Xinmaining Capsule (*Xueshuan Xinmaining Jiaonang*)

## 血栓心脉宁胶囊

### Sample source

Commercially available Xueshuan Xinmaining Capsules

### Chemical reference substances

Rutin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 100080-200306)

### Preparation of test solution

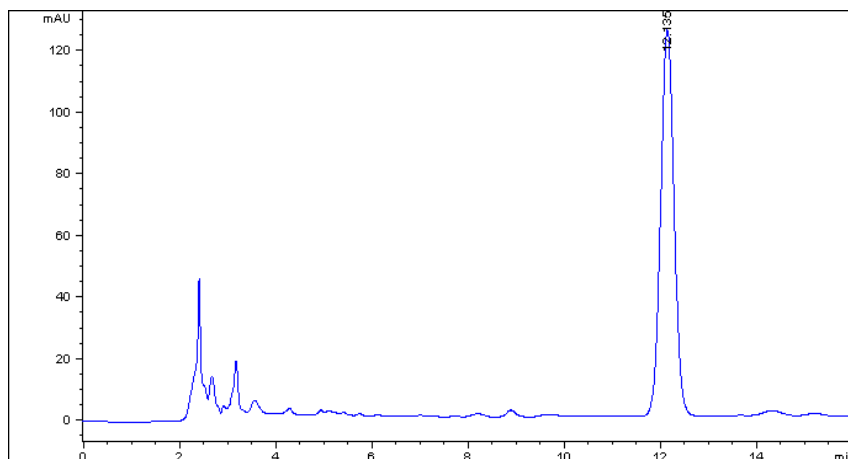
Mix the content of the capsules well, accurately weigh 0.5 g in a 50 mL volumetric flask. Add 45 mL of methanol, stopper tightly, treat ultrasonically for 30 minutes, allow to cool, add methanol to volume, mix well.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-1.82 % glacial acetic acid (40:60)
- Detector wavelength: 257 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Rutin	3.854	12.135	125.24	2432.3	9269	1.04

# Yatong Yili Pills (*Yatong Yili Wan*) – 牙痛一粒丸

## Sample source

Commercially available Yatong Yili Pills

## Chemical reference substances

1. Cinobufagin, 2. Bufogenin  
(National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 110803-200203, 2. 110718-200207)

## Preparation of test solution

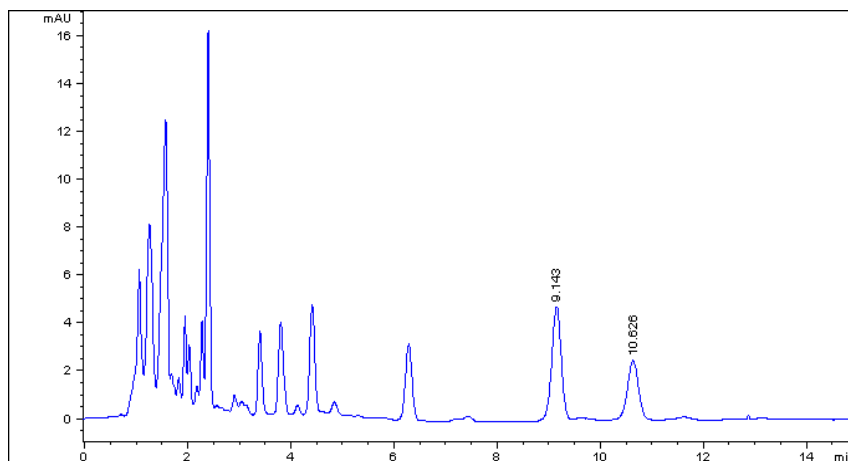
Grind the pills to a fine powder, accurately weigh 75 mg of the powder in a stoppered conical flask, accurately add 5 mL of methanol, stopper tightly, and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with methanol and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-water (45:55)
- Detector wavelength: 296 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Cinobufagin	6.619	9.143	4.70	58.7	12390	0.97
Bufogenin	7.855	10.626	2.44	35.2	12417	0.98

# Yanhusuo (*Rhizoma Corydalis*) – 延胡索

## Sample source

Commercially available Yanhusuo

## Chemical reference substances

Tetrahydropalmatine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0726-200208)

## Preparation of test solution

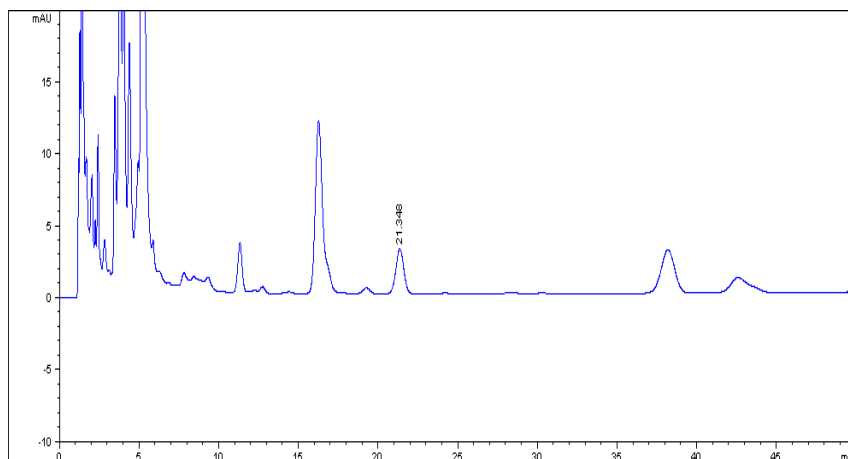
Accurately weigh 0.5 g of the powder in a flat-bottomed flask, accurately add 50 mL of a mixture of strong ammonia TS and methanol (1:20), weigh, allow to soak for 1 hour and then heat under reflux for 1 hour, allow to cool and weigh again, replenish the lost solvent with the above mixture, mix well and filter. Evaporate accurately 25 mL of the successive filtrate to dryness, dissolve the residue in methanol, transfer to a 5 mL volumetric flask, dilute with methanol to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5  $\mu$ m (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.1 % phosphoric acid (adjust to pH 6.5 with triethylamine) (55:45)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu$ L

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
tetrahydropalmatine	16.790	21.348	3.08	105.0	9102	0.997

# Yangxue Shengfa Jiaonan (*Yangxue Shengfa Jiaonang*)

## 养血生发胶囊

### Sample source

Commercially available Yangxue Shengfa Jiaonang

### Chemical reference substances

2,3,5,4'-tetrahydroxystibene-2-O-β-D-glucoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0844-200003)

### Preparation of test solution

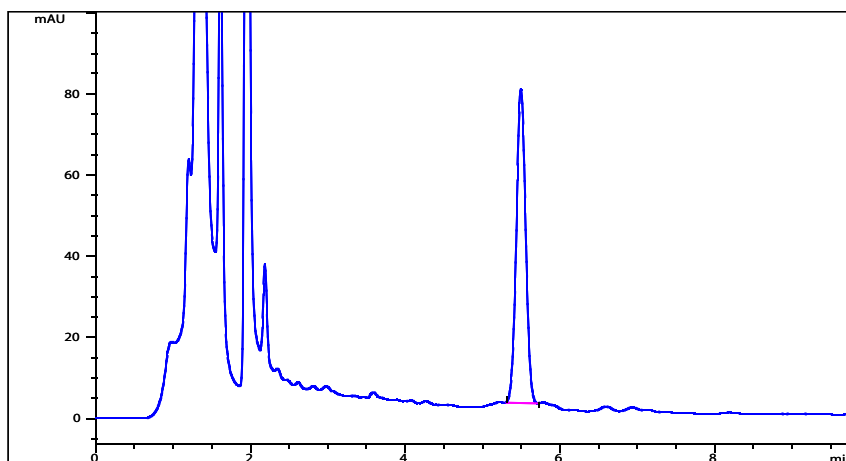
Grind the contents of the capsules to a fine powder and mix thoroughly. Accurately weigh 0.2 g in a stoppered conical flask, accurately add 10 mL of dilute ethanol TS and weigh. Heat under reflux for 30 minutes, allow to cool, replenish the lost weight with 50 % ethanol and mix well. Filter, and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-water (19:81)
- Detector wavelength: 320 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
2,3,5,4'-Tetrahydroxystibene-2-O-β-D-glucoside	3.580	5.496	77.33	647.9	10246	1.00

# Yangyin Qingfei Pills (*Yangyin Qingfei Wan*) – 养阴清肺丸

## Sample source

Commercially available Yangyin Qingfei Pills

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0708-200205)

## Preparation of test solution

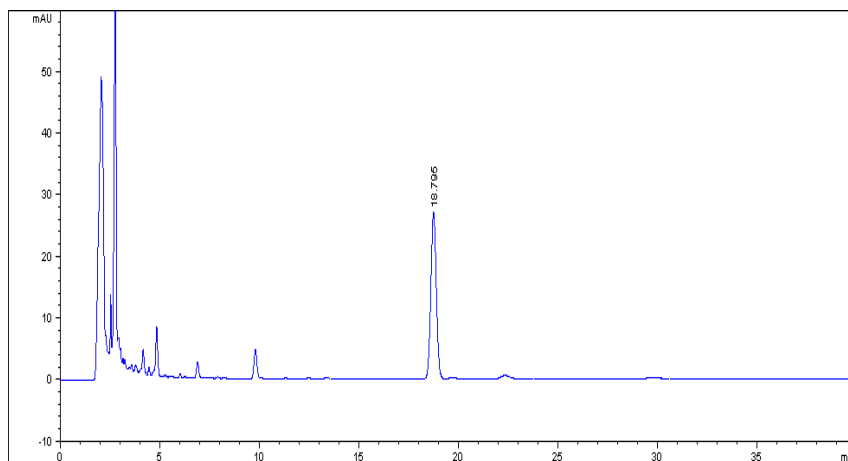
Cut the pills into pieces, mix well and accurately weigh 1 g, accurately add 50 mL of methanol, stopper tightly, weigh, heat under reflux for 1 hour, allow to cool, weigh, heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with methanol, shake well, filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-glacial acetic acid-water (33:2:67)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	6.518	18.795	26.97	510.0	22745	1.03

# Wild Chrysanthemum Flower (*Flos Chrysanthemi Indici*) – 野菊花

## Sample source

Commercially available Wild Chrysanthemum Flower

## Chemical reference substances

Buddleoside (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

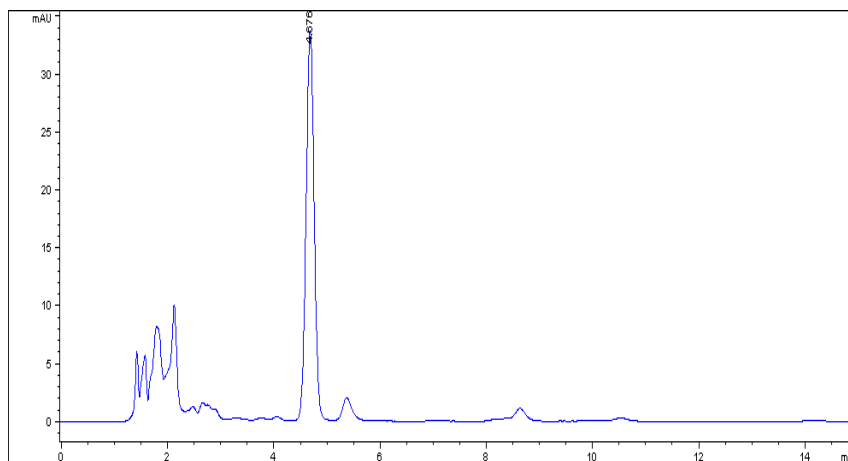
Accurately weigh 0.25 g of the powder in a stoppered conical flask, accurately add 100 mL of methanol, heat under reflux for 3 hours, allow to cool and weigh again, replenish the lost solvent with methanol and mix well. Filter with a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-water-glacial acetic acid (52:46:2)
- Detector wavelength: 334 nm
- Flow rate: 1.0 mL/min
- Inject volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
buddleoside	2.897	4.676	33.66	353.4	4635	1.02



# Yinianjin Powder (*Yinianjin*) – 一捻金

## Sample source

Commercially available Yinianjin Powder

## Chemical reference substances

Emodin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110756-200210)

## Preparation of test solution

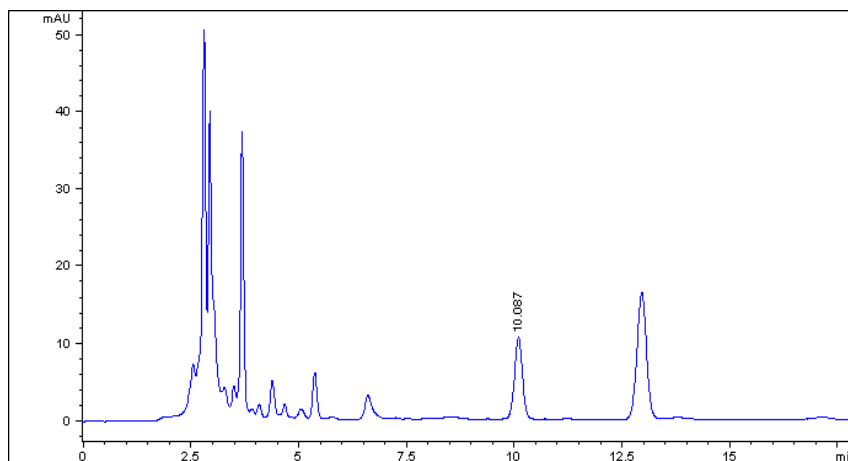
Grind the powder to a fine powder and mix thoroughly, accurately weigh 0.8 g in a stoppered conical flask, accurately add 20 mL of methanol, stopper tightly and weigh. Heat under reflux for 1 hour, allow to cool, weigh again, and replenish the lost weight with methanol. Mix well, filter, accurately measure 5 mL of the filtrate in a 100 mL round-bottomed flask and evaporate the solvent. Add 20 mL of 2.5 mol/L solution of sulfuric acid to the residue, treat ultrasonically for 10 minutes, heat on a water bath for 1 hour and cool immediately. Extract with four 25 mL quantities of ether, combine the ether extracts, wash with 15 mL of water and discard the washings. Evaporate the ether at a low temperature, dissolve the residue with methanol, transfer to a 25 mL volumetric flask, dilute with methanol to volume and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: Hypersil ODS, 4.6 x 250 mm, 5 mm (7991618-584)
- Column temperature: 25 °C
- Mobile phase: methanol-0.05 % phosphoric acid (80:20)
- Detector wavelength: 289 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Emodin	3.035	10.087	10.54	135.7	14737	0.99

# Yiqing Granules (*Yiqing Keli*) – 一清颗粒

## Sample source

Commercially available Yiqing Granules

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

## Preparation of test solution

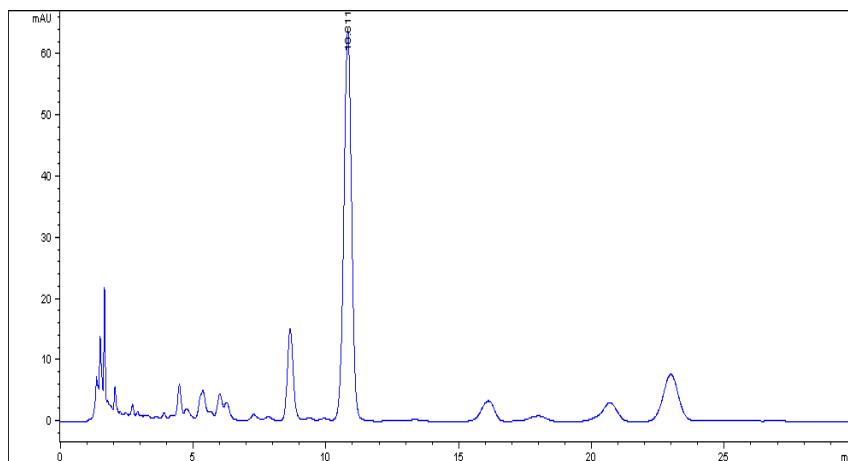
Grind the granules to a fine powder and mix thoroughly. Accurately weigh 0.75 g of the powder in a 100 mL volumetric flask. Add 10 mL of methanol and treat ultrasonically for 10 minutes, allow to cool, dilute with water to volume, mix well, centrifuge and use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.2 mol/L sodium dihydrogen phosphate (adjust pH with phosphoric acid to 2.7) (42:58)
- Detector wavelength: 275 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	6.207	10.811	63.79	1289.2	6737	0.98

# Yiganning Granules (*Yiganning Keli*) – 乙肝宁颗粒

## Sample source

Commercially available Yiganning Granules

## Chemical reference substances

Astragaloside IV (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0781-9807)

## Preparation of test solution

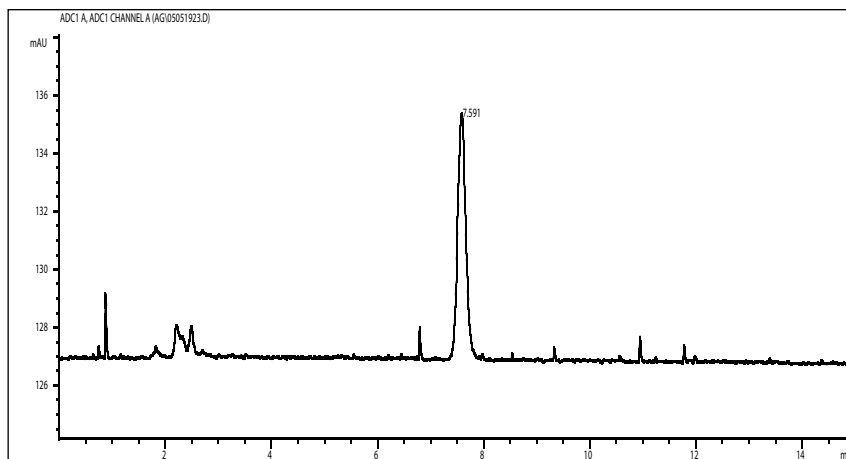
Grind the granules to a fine powder, accurately weigh 5 g and dissolve in 20 mL of water. Extract with four 20 mL quantities of n-butanol saturated with water, combine the n-butanol extracts, wash with two 20 mL quantities of ammonia TS, and wash again with two 20 mL quantities of water saturated with n-butanol. Separate the n-butanol layer, evaporate to dryness, dissolve the residue in a quantity of methanol, transfer to a 5 mL volumetric flask, dilute to volume with methanol. Mix well, filter, and use the filtrate as the solution.

## Chromatographic conditions

- Column: ZORBAX Extend C18 4.6×250 mm, 5 μm (770450-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (35:65)
- Evaporator tube temperature: 80 °C, Nebulizing temperature: 50 °C, Air flow rate: 1.5 mL/min
- Flow rate: 1.0 mL/min

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD PL-ELS 1000



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
astragaloside IV	2.036	7.591	8.49	91.0	11966	1.06

# Yiqi Yangxue Mixture (*Yiqi Yangxue Koufuye*) – 益气养血口服液

## Sample source

Commercially available Yiqi Yangxue Mixture

## Chemical reference substances

Icariine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0737-9910)

## Preparation of test solution

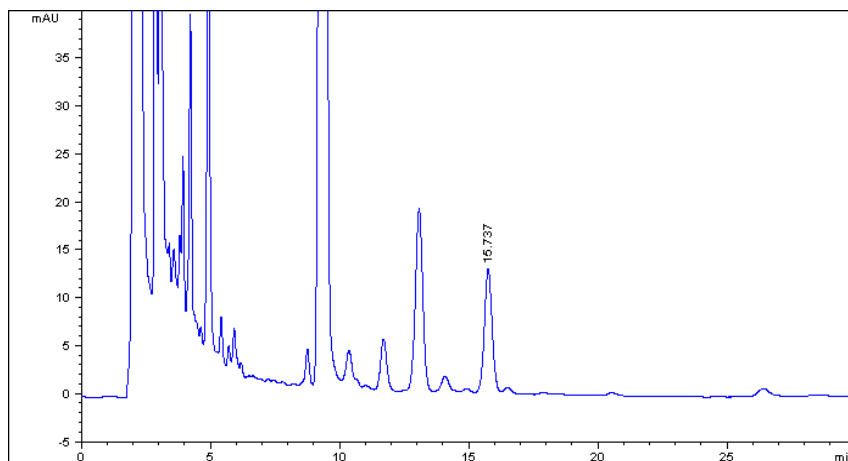
Accurately measure 3 mL of the mixture in a 10 mL volumetric flask, add a quantity of methanol, treat ultrasonically for 30 minutes, allow to cool, dilute with methanol to volume, mix well, filter the supernatant through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (990967-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.05 % phosphoric acid (26:74)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Icariine		15.737	13.02	276.0	13372	1.02

# Yinhuang Mixture (*Yinhuang Koufuye*) – 银黄口服液

## Sample source

Commercially available Yinhuang Mixture

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

## Preparation of test solution

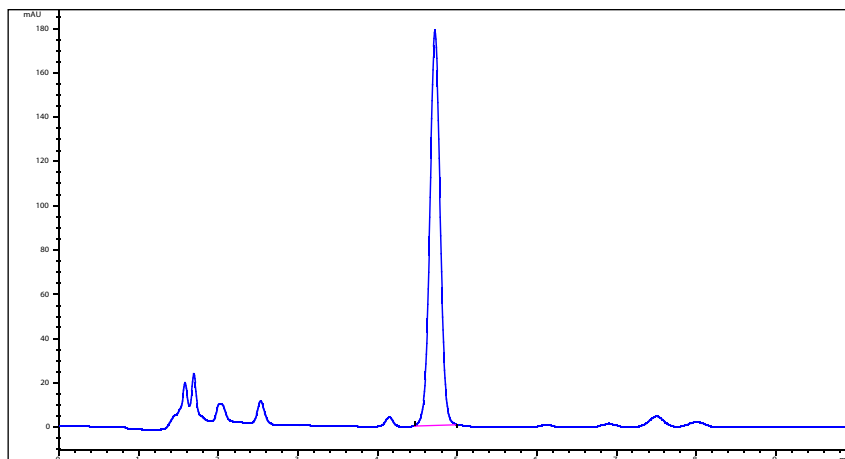
Accurately measure 0.2 mL of the mixture in a 10 mL volumetric flask, dilute with water to volume and mix well. Accurately measure 1.0 mL in a 10 mL volumetric flask, dilute with 50 % methanol to volume, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5  $\mu$ m (883975-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water-phosphoric acid (50:50:0.2)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu$ L

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Baicalin		4.720	178.56	1593.3	6844	0.99

# Yinhuang Mixture (*Yinhuang Koufuye*) – 银黄口服液

## Sample source

Commercially available Yinhuang Mixture

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110753-200212)

## Preparation of test solution

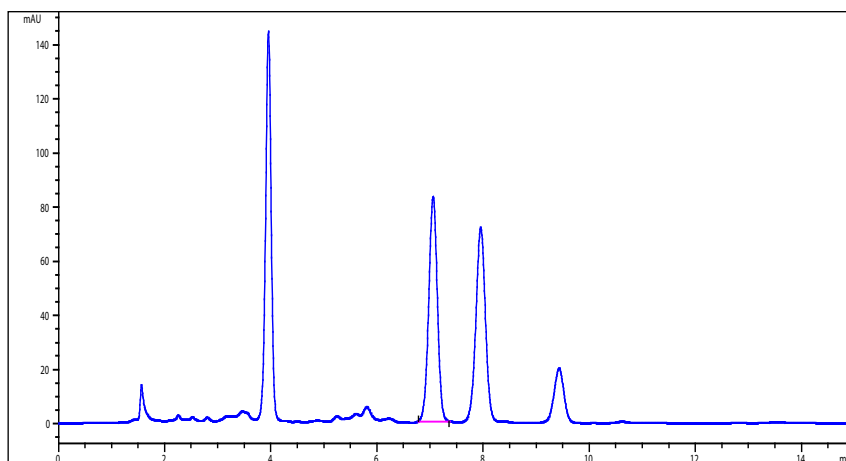
Accurately measure 0.2 mL of the mixture in a 10 mL amber volumetric flask, dilute with 50 % methanol to volume, mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 35 °C
- Mobile phase: acetonitrile-0.4 % phosphoric acid (10:90)
- Detector wavelength: 327 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid		7.060	83.02	932.7	9569	0.98

# Yinqiao Jiedu Capsules (*Yinqiao Jiedu Jiaonang*) – 银翘解毒胶囊

## Sample source

Commercially available Yinqiao Jiedu Capsules

## Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110753-200212)

## Preparation of test solution

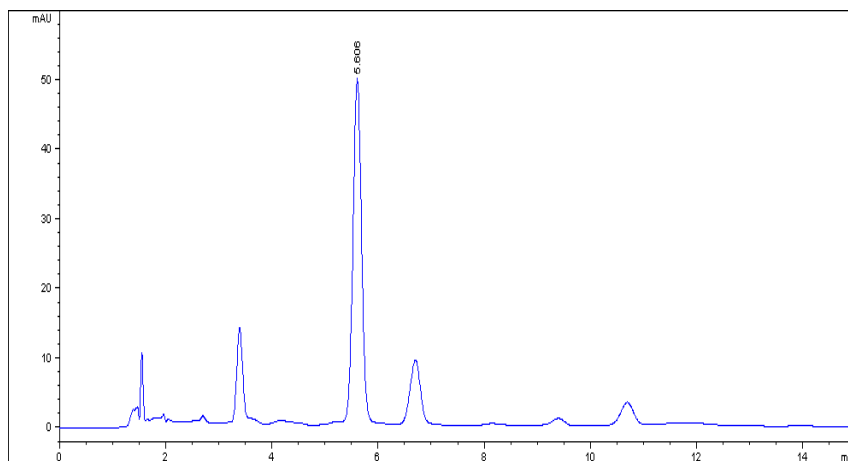
Grind the contents of the capsules to a fine powder, accurately weigh 0.25 g in a 50 mL amber volumetric flask, accurately add 40 mL of 50 % methanol, treat ultrasonically for 30 minutes, allow to cool, dilute with 50 % methanol to volume, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water-glacial acetic acid-triethylamine (18:85:1:0.3)
- Detector wavelength: 324 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	2.737	5.606	49.43	545.1	6024	1.02

# Ginkgo Leaf (*Folium Ginkgo*) – 银杏叶

## Sample source

Commercially available Ginkgo Leaf (Pizhou, Jiangsu province)

## Chemical reference substances

1. Quercetin, 2. Kaempferol, 3. Isorhamnetin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 0081-9905, 2. 0864-9901)

## Preparation of test solution

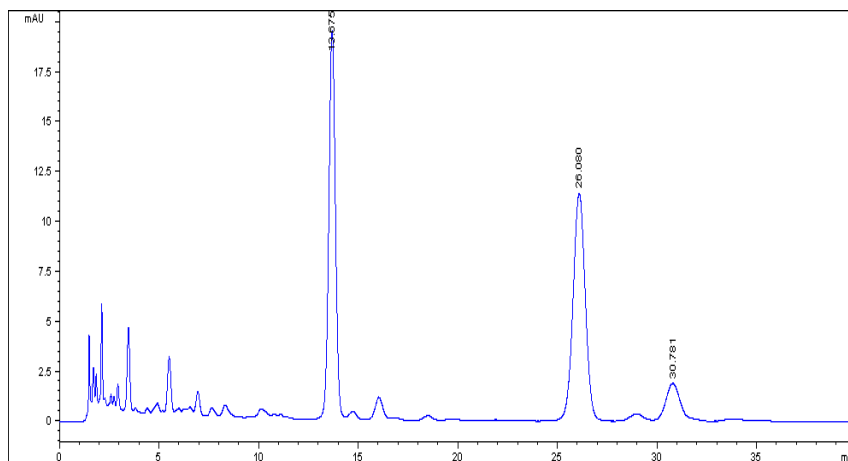
Accurately weigh 1 g of the powder in a Soxhlet extractor, add chloroform and heat under reflux for 2 hours. Discard the chloroform solution, evaporate the residue to dryness, add methanol, heat under reflux for 4 hours and evaporate the extract to dryness. Dissolve the residue in 25 mL of a mixture of methanol and 25 % hydrochloric acid (4:1), heat under reflux for 30 minutes, allow to cool, transfer to a 50 mL volumetric flask, add methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.4 % phosphoric acid (45:55)
- Detector wavelength: 360 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Quercetin	8.117	13.675	19.37	439.4	8485	1.01
Kaempferol	16.386	26.08	11.30	473.1	9043	1.00
Isorhamnetin	19.521	30.781	1.78	82.1	10037	1.05



# Ginkgo Leaf (*Folium Ginkgo*) – 银杏叶

## Sample source

Commercially available Ginkgo Leaf (Pizhou, Jiangsu province)

## Chemical reference substances

Ginkgolide A, Ginkgolide B, Ginkgolide C, and Bilobalide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0862-200004, 110863-200305, 110864-200304, 110865-200404)

## Preparation of test solution

Accurately weigh 1.5 g of the powder in a Soxhlet extractor, add petroleum ether (30-60 °C) and heat under reflux on a water bath at 70 °C for 1 hour. Discard the petroleum ether solution, evaporate the residue and the extractor to dryness at 60 °C in an oven, add methanol, heat under reflux for 6 hours, evaporate the extract to dryness, dissolve the residue in methanol, transfer accurately to a 10 mL volumetric flask, treat ultrasonically for 30 minutes, allow to cool, add methanol to volume, mix well, and allow to stand.

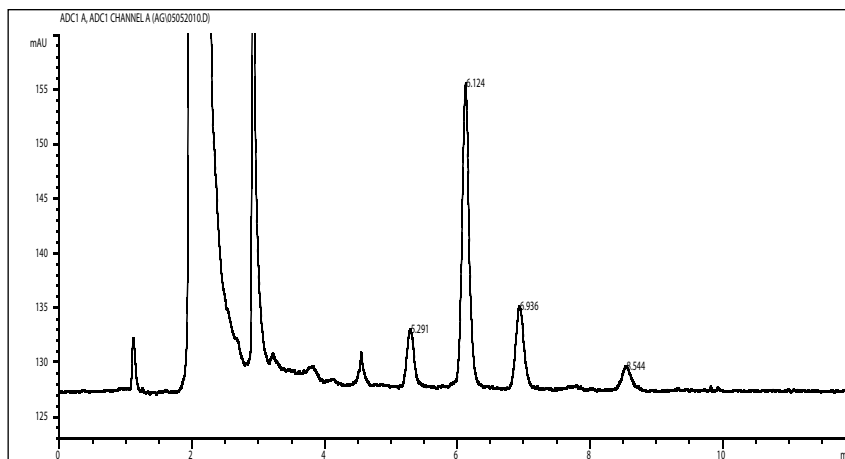
Accurately measure 5 mL of the supernatant and apply to an acidic alumina column, elute with 25 mL of methanol, collect the eluent, evaporate to dryness, dissolve the residue in 5 mL of methanol, transfer to a 10 mL volumetric flask, add 4.5 mL of water, treat ultrasonically for 30 minutes, cool, add methanol to volume, mix well and filter.

## Chromatographic conditions

- Column: ZORBAX Extend C18 4.6×250 mm, 5 µm (770450-902)
- Column temperature: 25 °C
- Mobile phase: methanol-tetrahydrofuran-water (25:10:65)
- Evaporator tube temperature: 80 °C, Nebulizing temperature: 50 °C, Air flow rate: 1.2SLM
- Flow rate: 1.0 ml/min
- Inject volume: 10 µl

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD PL-ELS 1000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
bilobalide	1.45	6.124	27.20	192.9	17704	1.099
ginkgolide A	1.776	6.939	7.12	57.9	16626	1.103
ginkgolide B	2.418	8.545	2.21	22.7	17585	0.953
ginkgolide C	1.116	5.291	4.92	33.1	13214	1.100

# Ginkgo Tablets (*Tabellae Folium Ginkgo*) – 银杏叶片

## Sample source

Commercially available Ginkgo Tablets

## Chemical reference substances

1. Quercetin, 2. Kaempferol, 3. Isorhamnetin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 0081-9905, 2. 0864-9901)

## Preparation of test solution

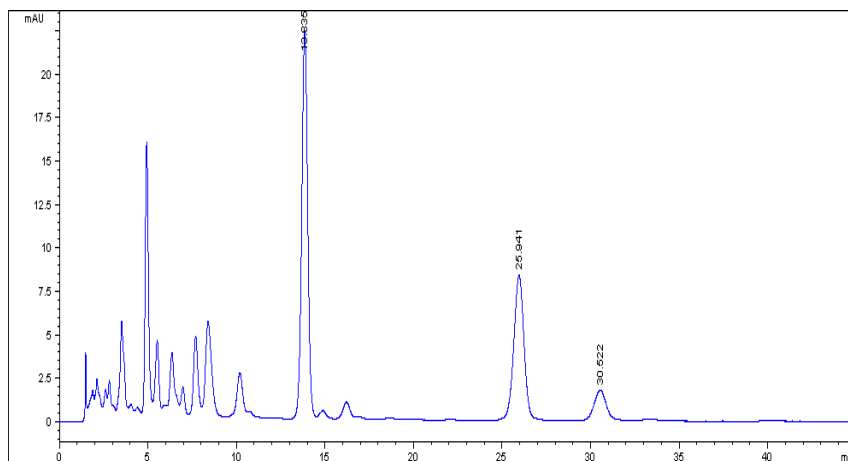
Accurately weigh 10 tablets, remove the coatings and grind to a fine powder. Accurately weigh 0.4 g of the powder in a stoppered conical flask, accurately add 20 mL of methanol, stopper tightly, weigh and treat ultrasonically for 20 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 5 mL of the filtrate in a 100 mL conical flask, add 10 mL of methanol, 5 mL of 25 % solution of hydrochloride acid, mix well, heat under reflux on a water bath for 30 minutes, cool immediately to room temperature, transfer to a 50 mL volumetric flask, dilute with methanol to volume, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.4 % phosphoric acid (45:55)
- Detector wavelength: 360 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Quercetin	8.224	13.835	22.30	520.0	8448	1.02
Kaempferol	16.294	25.941	8.28	324.4	10462	0.97
Isorhamnetin	19.348	30.522	1.72	78.5	10567	1.03

# Ginkgo Tablets (*Tabellae Folium Ginkgo*) – 银杏叶片

## Sample source

Commercially available Ginkgo Tablets

## Chemical reference substances

Ginkgolide A, Ginkgolide B, Ginkgolide C, and Bilobalide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0862-200004, 110863-200305, 110864-200304, 110865-200404)

## Preparation of test solution

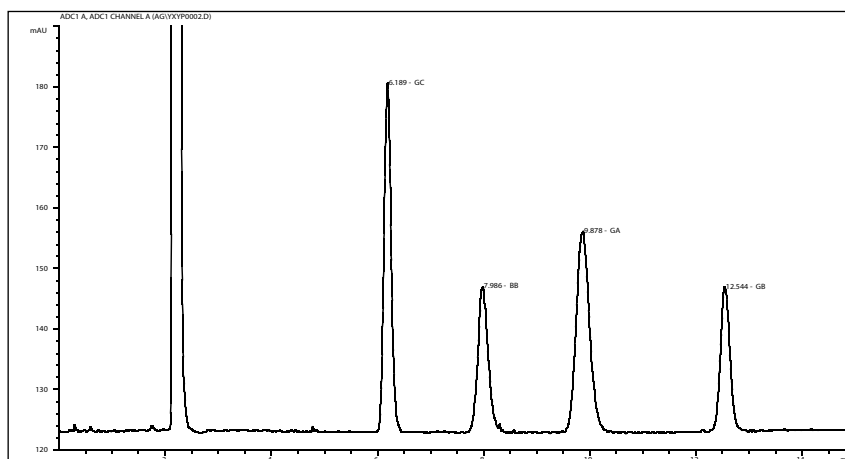
Accurately weigh 20 tablets, remove the coatings and grind to a fine powder. Accurately weigh the powder, accurately add 50 mL of methanol, stopper tightly, weigh and treat ultrasonically for 20 minutes, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 20 mL of the filtrate, evaporate the methanol to dryness, dissolve the residue in 10 mL of water, heat on a water bath, add 2 drop of a 2 % solution of hydrochloric acid, extract with four 10 mL quantities of ethyl acetate by shaking, combine the extracts, wash with 20 mL of a 5 % solution of sodium acetate, separate the layer of sodium acetate, wash with 10 mL of ethyl acetate. Combine the ethyl acetate extracts and washings, wash with two 20 mL quantities of water, combine the water washings, wash with 10 mL of ethyl acetate, combine the ethyl acetate washings, evaporate to dryness, dissolve the residue in methanol in a 5 mL volumetric flask, dilute with methanol to the volume and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 50 °C
- Mobile phase: A: 1 % n-propanol in water, B: 1 % n-propanol in tetrahydrofuran; 0-6 min: 30-15 %B, 6-10 min: 15-30 %B, 10-15 min: 30 %B.
- Evaporator tube temperature: 80 °C, Nebulizing temperature: 50 °C, Air flow rate: 1.2SLM
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD PL-ELS 1000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Bilobalide	2.194	7.986	24.04	320.6	8833	1.10
Ginkgolide A	2.951	9.878	33.05	571.4	7415	1.06
Ginkgolide B	4.018	12.544	23.75	291.6	24578	1.10
Ginkgolide C	1.476	6.189	57.41	522.7	10700	1.10

# Ginkgo Biloba Leaf Extract (*Extractum Folium Ginkgo Siccus*)

## 银杏叶提取物

### Sample source

Commercially available Ginkgo Biloba leaf Extract

### Chemical reference substances

1. Quercetin, 2. Kaempferol, 3. Isorhamnetin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 0081-9905, 2. 0864-9901)

### Preparation of test solution

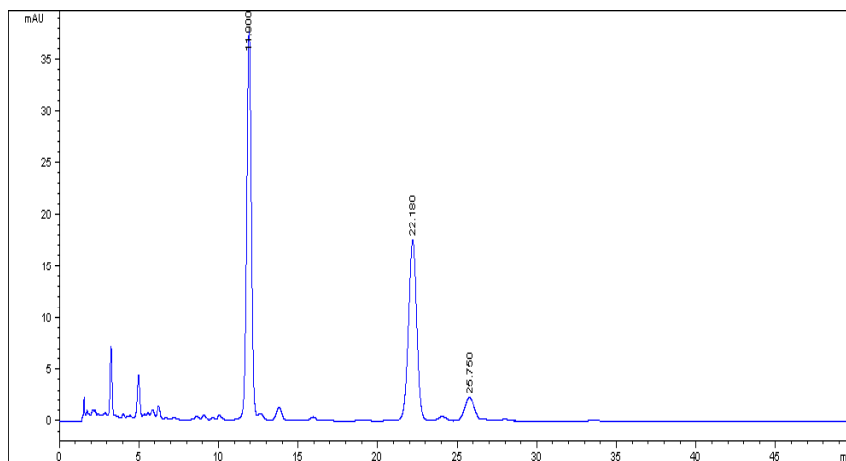
Accurately weigh 35 mg and extract with 25 mL of a mixture of methanol and 25 % hydrochloride acid solution (4:1) under reflux on a water bath for 30 minutes. Cool immediately to room temperature, transfer to a 25 mL volumetric flask, dilute with methanol to volume, shake well, filter and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.4 % phosphoric acid (45:55)
- Detector wavelength: 360 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Quercetin	6.937	11.900	37.65	770.8	8132	0.99
Kaempferol	13.787	22.18	17.42	625.4	9061	0.98
Isorhamnetin	16.167	25.75	2.20	92.6	8816	1.05

# Ginkgo Biloba Leaf Extract (*Extractum Folium Ginkgo Siccus*)

## 银杏叶提取物

### Sample source

Commercially available Ginkgo Leaf (Pizhou, Jiangsu province)

### Chemical reference substances

Ginkgolide A, Ginkgolide B, Ginkgolide C, and Bilobalide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0862-200004, 110863-200305, 110864-200304, 110865-200404)

### Preparation of test solution

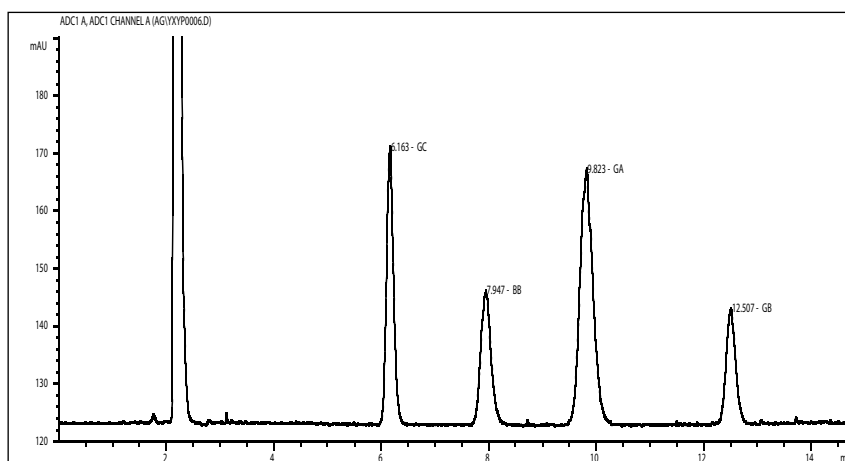
Accurately weigh 10 g sample, extract with 10 mL of water on a water bath, add 2 drops of a 2 % hydrochloride acid solution, extract by shaking with one 15 mL and three 10 mL quantities of ethyl acetate, combine the ethyl acetate extracts and wash with 5 % sodium acetate solution. Separate the sodium acetate layer, wash again with 10 mL of ethyl acetate. Combine the ethyl acetate extracts and ethyl acetate washings, wash with two 20 mL quantities of water, separate the water layer and wash with 10 mL ethyl acetate. Combine all the ethyl acetate solutions and evaporate the solvent to dryness. Dissolve the residue in methanol, transfer to a 5 mL volumetric flask, add methanol to volume, shake well, filter and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 50 °C
- Mobile phase: A: 1 % n-propanol in water, B: 1 % n-propanol in tetrahydrofuran; 0-6 min: 30-15 %B, 6-10 min: 15-30 %B, 10-15 min: 30 %B.
- Evaporator tube temperature: 80 °C
- Nebulizing temperature: 50 °C
- Air flow rate: 1.2SLM
- Flow rate: 1.0 mL/min
- Inject volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
bilobalide	2.179	7.947	22.95	295.6	8895	1.10
ginkgolide A	2.929	9.823	44.27	736.8	8010	1.10
ginkgolide B	4.003	12.507	19.89	241.4	24871	1.08
ginkgolide C	1.465	6.163	47.70	426.0	10735	1.10

# Poppy Capsules (*Pericarpium Papaveris*) – 罂粟壳

## Sample source

Commercially available Poppy Capsule

## Chemical reference substances

Morphine (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

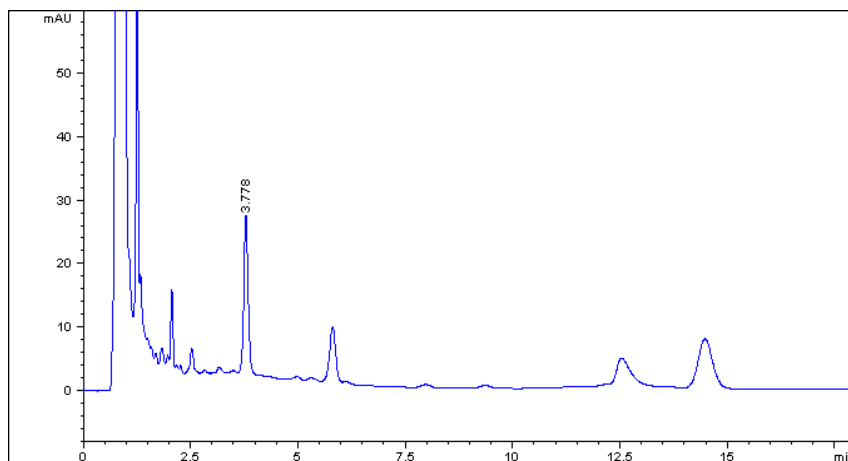
Accurately weigh 0.5 g of the powder in a 50 mL volumetric flask, accurately add 25 mL of 20 % methanol and 5 % acetic acid, stopper tightly, weigh, treat ultrasonically for 30 minutes, allow to cool, weigh again and replenish the lost solvent with 20 % methanol and 5% acetic acid, mix well and stand, take the supernatant, filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8, 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (993967-906)
- Column temperature: 35  $^{\circ}\text{C}$
- Mobile phase: acetonitrile-0.01 mol/L potassium dihydrogen phosphate-5 mmol/L heptane sodium sulfonate (18:40:42)
- Detector wavelength: 220 nm
- Flow rate: 1.0 mL/min
- Injection volume: 2  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Morphine	2.778	3.778	24.54	176.2	6948	1.04

# Yupingfeng Mixture (*Yupingfeng Koufuye*) – 玉屏风口服液

## Sample source

Commercially available Yupingfeng Mixture

## Chemical reference substances

Astragaloside IV (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0781-9807)

## Preparation of test solution

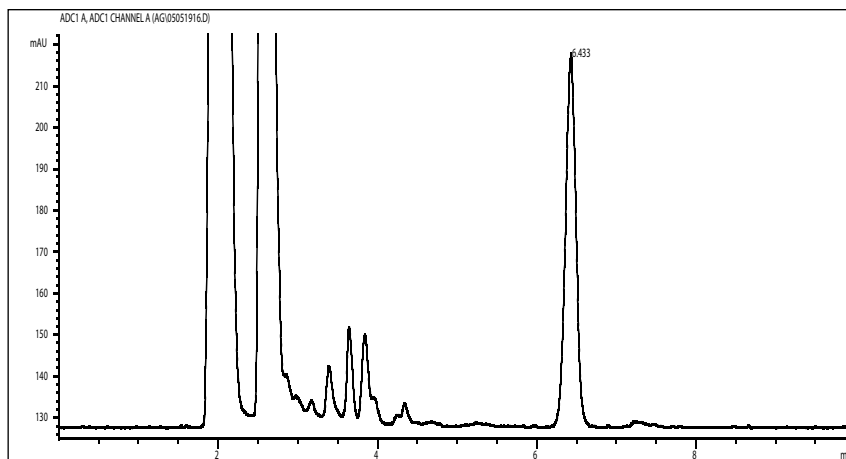
Accurately measure 20 mL of the mixture, extract with five 25 mL quantities of n-butanol saturated with water, combine the extracts and wash with three 20 mL quantities of ammonia TS. Evaporate the solvent, dissolve the residue in methanol, transfer to a 10 mL volumetric flask and dilute with methanol to volume. Mix well, centrifuge, and use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX Extend C18, 4.6×250 mm, 5 μm (770450-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (35:65)
- Evaporator tube temperature: 80 °C, Nebulizing temperature: 50 °C, Air flow rate: 1.5SLM
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD PL-ELS 1000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Astragaloside IV	1.573	6.433	90.27	818.4	11558	0.97

# Yueju Pills (*Yueju Wan*) – 越鞠丸

## Sample source

Commercially available Yueju Pills

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110749-200309)

## Preparation of test solution

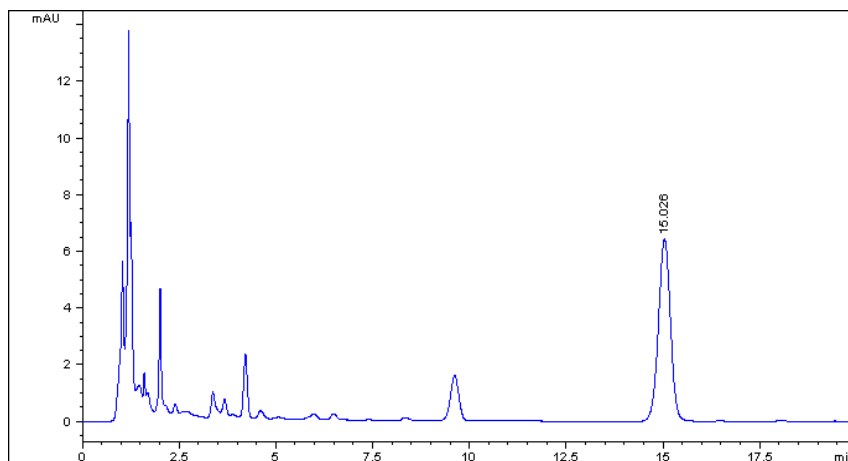
Grind a quantity of the pills to a fine powder. Accurately weigh 0.05 g in a stoppered conical flask, accurately add 25 mL of 50 % methanol, stopper tightly and weigh. Treat ultrasonically for 30 minutes, allow to cool, weigh again and replenish the lost weight with 50 % methanol. Mix well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-water-phosphoric acid (9:91:0.1)
- Detector wavelength: 240 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide	11.522	15.026	6.40	136.3	11655	0.98



# Zaizao Shengxue Tablets (*Zaizao Shengxue Pian*) – 再造生血片

## Sample source

Commercially available Zaizao Shengxue Tablets

## Chemical reference substances

1. Psoralen, 2. Isopsoralen (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1. 110739-200309, 2. 110738-200309)

## Preparation of test solution

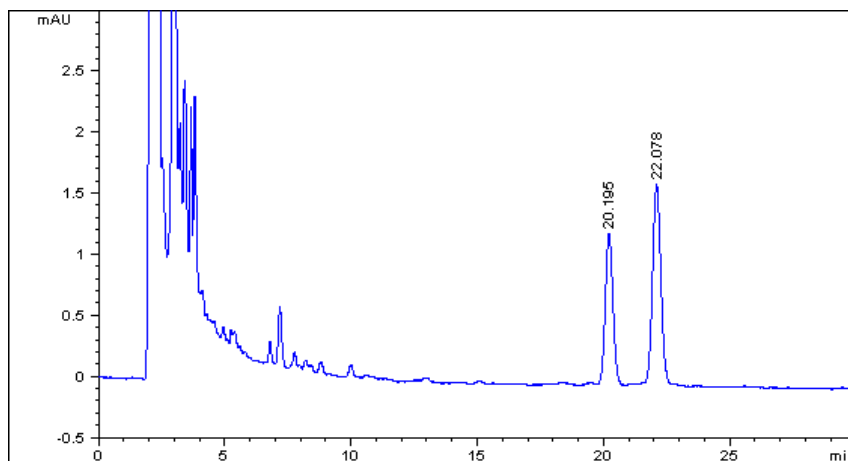
Remove the coatings from 20 tablets grind to a fine powder. Accurately weigh about 1 g of the powder in a stoppered conical flask. Accurately add 25 mL of methanol, stopper tightly and weigh accurately. Treat ultrasonically for 30 minutes, allowed to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 1 mL of the filtrate in a 10 mL volumetric flask, add methanol to volume, mix well and filter, and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 μm (880975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.125 % phosphoric acid (30:70)
- Detector wavelength: 247 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Psoralen	7.078	20.195	1.24	26.0	21369	1.05
Isopsoralen	7.831	22.078	1.64	38.2	21513	1.05

# Zangliang Pills (*Zangliang Wan*) – 脏连丸

## Sample source

Commercially available Zangliang Pills

## Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110715-200212)

## Preparation of test solution

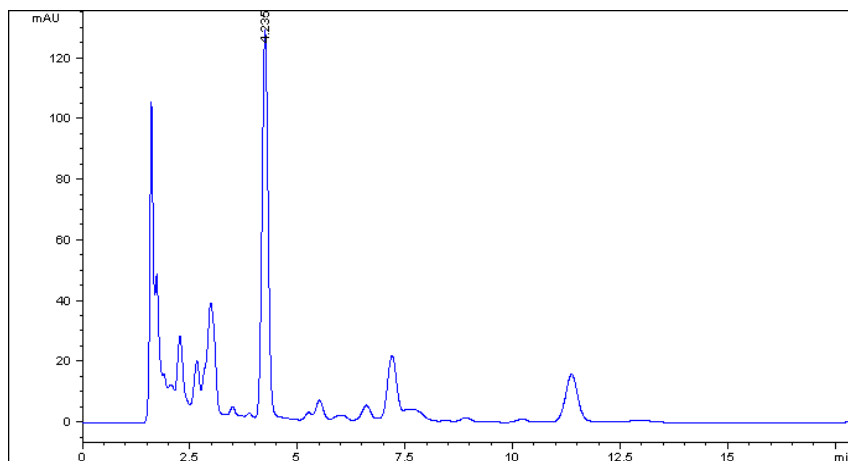
Grind the pills to a fine powder. Accurately weigh 0.25 g in a stoppered conical flask, accurately add 50 mL of methanol, weigh, and heat under reflux for 1 hour. Allow to cool, weigh again, replenish the lost weight with methanol and mix well. Centrifuge and use the supernatant as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883995-902)
- Column temperature: 25 °C
- Mobile phase: methanol-2 % glacial acetic acid (45:55)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	1.824	4.235	127.56	1246.3	4390	1.03

# Thunberg Fritillary Bulb (*Bulbus Fritillariae Thunbergii*) – 浙贝母

## Sample source

Commercially available Thunberg Fritillary Bulb

## Chemical reference substances

Peimine, Peinine

## Preparation of test solution

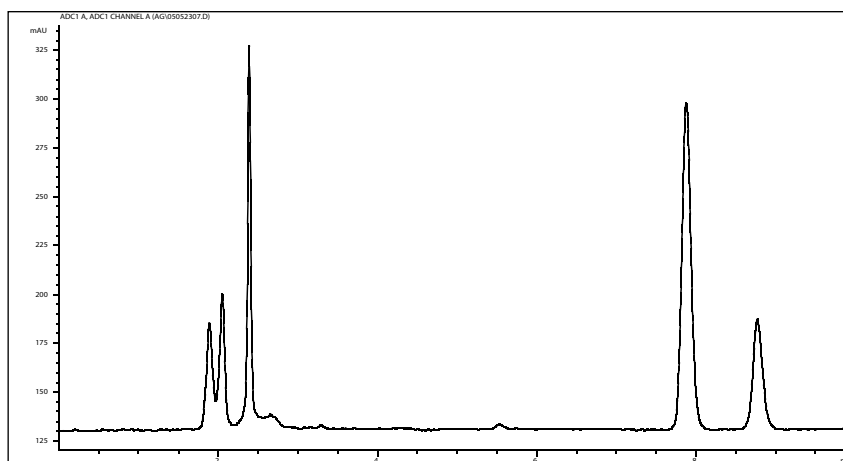
Accurately weigh 2 g of the powder in a flask, add 4 mL of strong ammonia TS and soak for 1 hour. Accurately add 40 mL of a mixture of chloroform and methanol (4:1), weigh, heat under reflux on a water bath at 80 °C for 2 hours, allow to cool and weigh again, replenish the lost solvent with the above mixture and filter. Accurately measure 10 mL of the filtrate and evaporate to dryness in an evaporating dish. Dissolve the residue with methanol, transfer to a 2 mL volumetric flask, dilute with methanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-3 % aqueous diethylamine solution (88:12)
- Evaporator tube temperature: 80°C, Nebulizing temperature: 50°C, Air flow rate: 1.5SLM
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD PL-ELS 1000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Peimine	2.151	7.878	165.28	1326.7	22300	1.106
Peinine	2.509	8.773	54.92	445.7	26574	1.102

# Zhenkening Syrup (*Zhenkening Tangjiang*) – 镇咳宁糖浆

## Sample source

Commercially available Zhenkening Syrup

## Chemical reference substances

Ephedrin hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products)

## Preparation of test solution

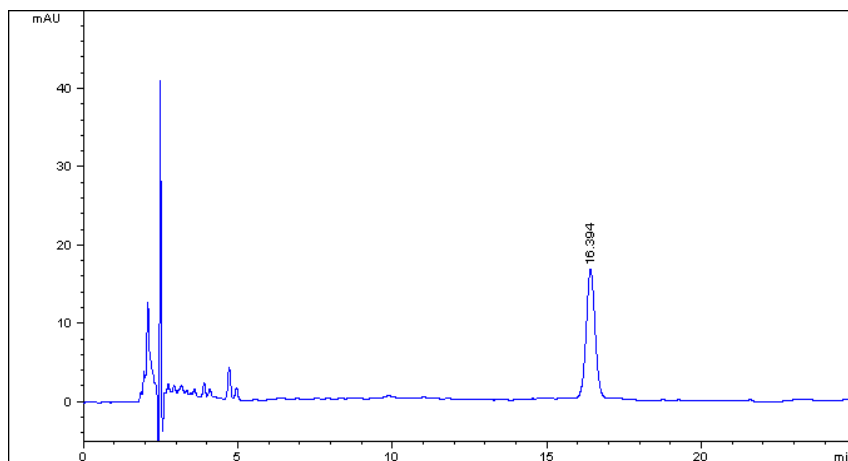
Accurately weigh 2.5 g of the syrup in a 25 mL volumetric flask, dilute with a 0.01 mol/L solution of hydrochloric acid to volume and mix well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: Reprosil C18 Pur 4.0×250 mm, 5 µm
- Column temperature: 25 °C
- Mobile phase: acetonitrile-20 mmol/L potassium dihydrogen phosphate (pH 3.0) (5:95)
- Detector wavelength: 210 nm
- Flow rate: 1.0 mL/min
- Injection volume: 2 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Ephedrin	7.197	16.394	16.41	325.5	16183	1.03

# Zhennaoning Capsules (*Zhennaoning Jiaonang*) – 镇脑宁胶囊

## Sample source

Commercially available Zhennaoning Capsules

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110752-200209)

## Preparation of test solution

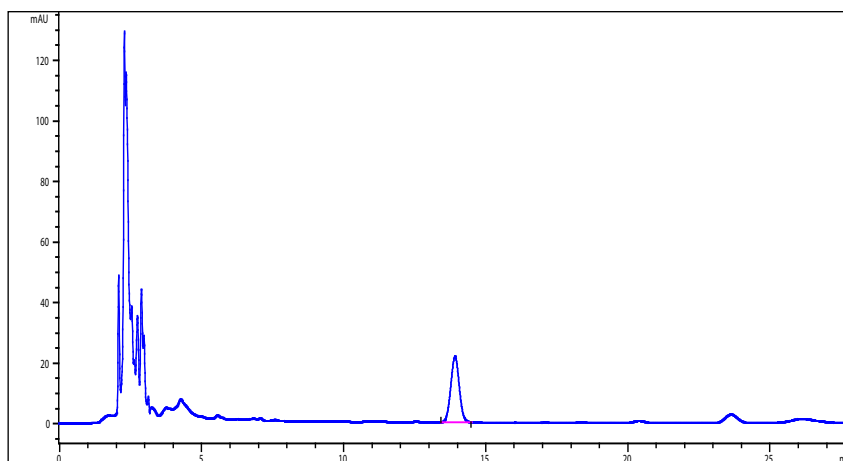
Mix the contents of the capsules well, accurately weigh 1 g, grind together with 1 g of kieselguhr, transfer to a Soxhlet extractor, add a quantity of petroleum ether (60-90 °C), heat under reflux on a water bath for 4 hours. Discard the petroleum ether extract and evaporate the remaining solvent in the residue. Transfer the residue with the extractor to a stoppered conical flask and accurately add 50 mL of 30 % ethanol, stopper tightly and weigh. Treat ultrasonically for 40 minutes, allow to cool, weigh again, replenish the lost weight with 30 % ethanol, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (25:75)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Puerarin	4.567	13.917	21.79	456.64	10479	1.03

# Zhenggu Tincture (*Zhenggu Shui*) – 正骨水

## Sample source

Commercially available Zhenggu Tincture

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0708-200205)

## Preparation of test solution

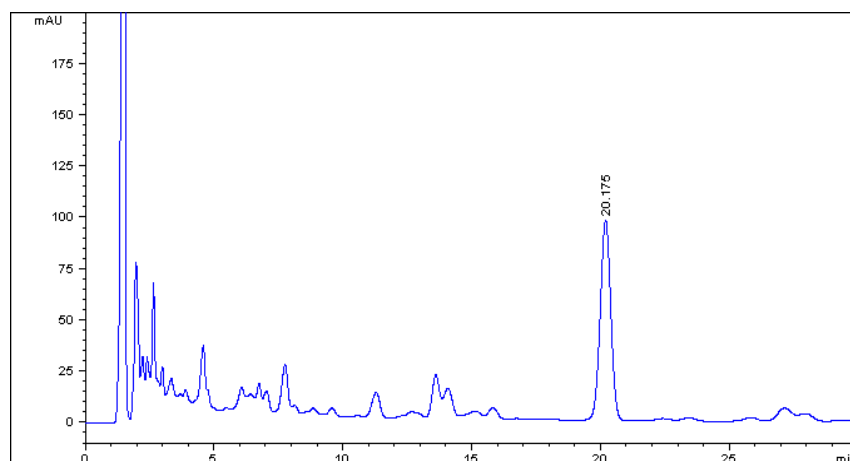
Accurately measure 10 mL of the tincture in a 25 mL volumetric flask, dilute with ethanol to volume and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water-triethylamine-phosphoric acid (28:72:0.1:0.1)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	15.813	20.175	97.30	2754.0	11819	0.99

# Zhibai Dihuang Pills (*Zhibai Dihuang Wan*) – 知柏地黄丸

## Sample source

Commercially available Zhibai Dihuang Pills

## Chemical reference substances

Paeonol (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0708-9704)

## Preparation of test solution

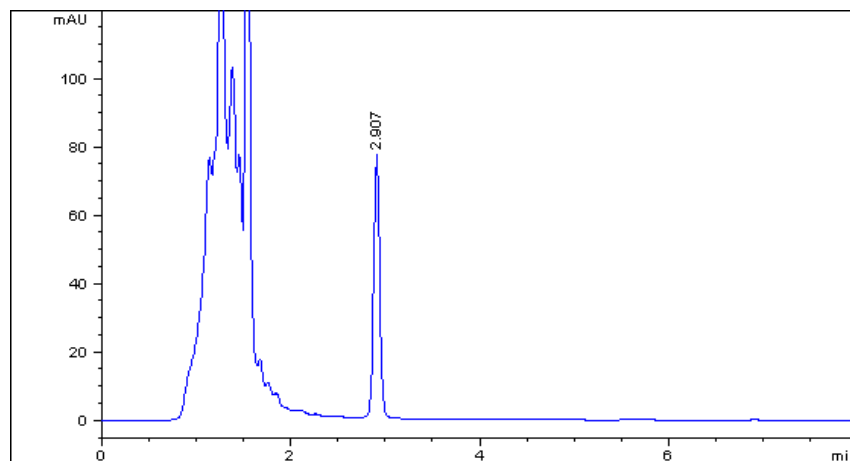
Cut the pills into pieces, accurately weigh 0.4 g in a stoppered conical flask, accurately add 50 mL of 50 % methanol, stopper tightly and weigh. Treat ultrasonically for 45 minutes, allow to cool, weigh again, replenish the lost weight with 50 % methanol, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (70:30)
- Detector wavelength: 274 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Paeonol	0.938	2.907	77.20	346.1	10534	1.01

# Zhibai Dihuang Pills (*Zhibai Dihuang Wan*) – 知柏地黄丸

## Sample source

Commercially available Zhibai Dihuang Pills

## Chemical reference substances

Loganin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 1111640-200205)

## Preparation of test solution

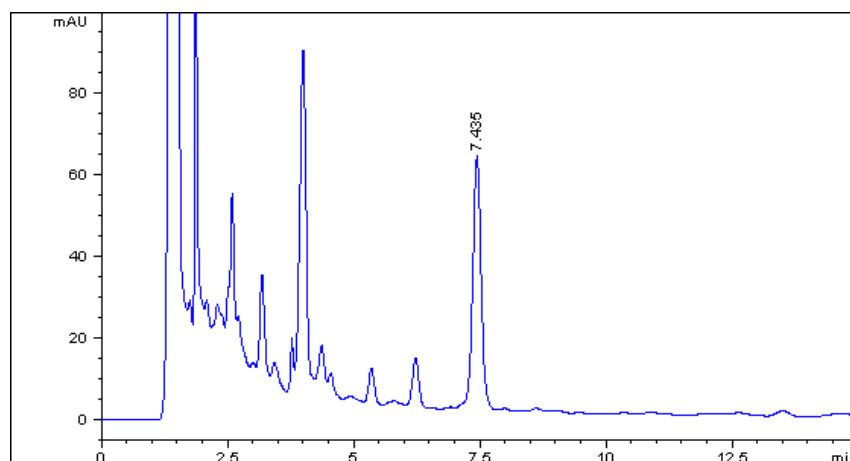
Cut the pills into pieces, accurately weigh 0.7 g in a stoppered conical flask, accurately add 25 mL of 50 % methanol and weigh. Treat ultrasonically for 15 minutes. Heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with 50 % methanol, shake well and filter. Accurately apply 10 mL of the filtrate to a column packed with neutral alumina (100-200 mesh, 4 g, 1 cm in inner diameter), elute with 50 mL of 40 % methanol, collect the eluents, evaporate to dryness and dissolve the residue in 50 % methanol. Transfer to a 5 mL volumetric flask, dilute with 50 % methanol to volume, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (70:30)
- Detector wavelength: 236 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Loganin	3.956	7.435	62.32	726.7	10458	1.01



# Common Anemarrhena Rhizome (*Rhizoma Anemarrhenae*) – 知母

## Sample source

Commercially available Common Anemarrhena Rhizome

## Chemical reference substances

Sarsasapogenin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 744-8701)

## Preparation of test solution

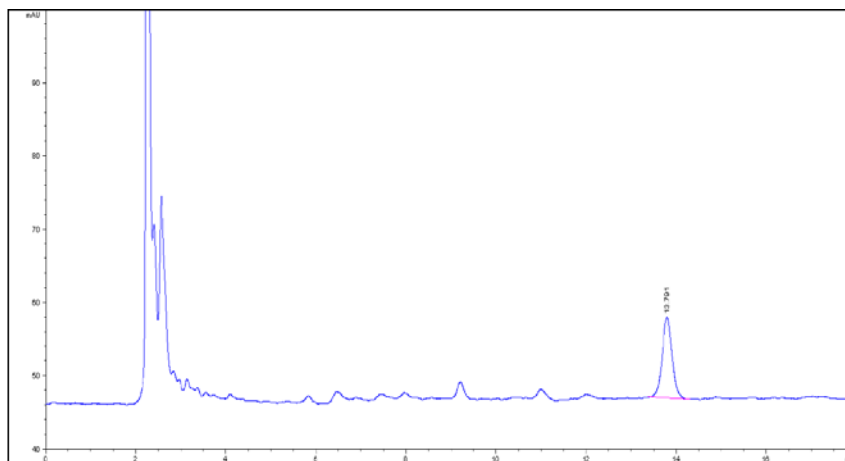
Accurately weigh 0.5 g of the powder in a stoppered conical flask, accurately add 25 mL of ethanol, weigh and allow to soak overnight. Treat ultrasonically for 40 minutes, allow to cool and weigh again, replenish the lost weight with ethanol and mix well. Evaporate accurately 10 mL of the filtrate to dryness, add 10 mL of water and 1 mL of hydrochloric acid, heat under reflux for 2 hours, allow to cool, add a 40 % solution of sodium hydroxide drop-wise, shaking after each drop, until to the color of the solution changes suddenly from orange-yellow to orange-red. Extract with two 30 mL quantities of chloroform, combine the extracts and evaporate to dryness. Dissolve the residue in methanol, transfer to a 10 mL volumetric flask, dilute to volume with methanol and mix well.

## Chromatographic conditions

- Column: ZORBAX XDB C18 4.6×250 mm, 5 µm (990967-902)
- Column temperature: 35 °C
- Mobile phase: methanol-water (95:5)
- Evaporator tube temperature: 65 °C
- Air flow rate: 2.0 mL/min
- Flow rate: 1.0 mL/min

## Chromatographic system

- Binary Pump (G1312A)
- Manual Injector (G1328B)
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD Alltech 2000
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU's)	n	USP T <sub>r</sub>
Sarsasapogenin	4.517	13.791	11.09	170.9	19919	0.99

# Zhizi Jinhua Pills (*Zhizi Jinhua Wan*) – 梔子金花丸

## Sample source

Commercially available Zhizi Jinhua Pills

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110749-200309)

## Preparation of test solution

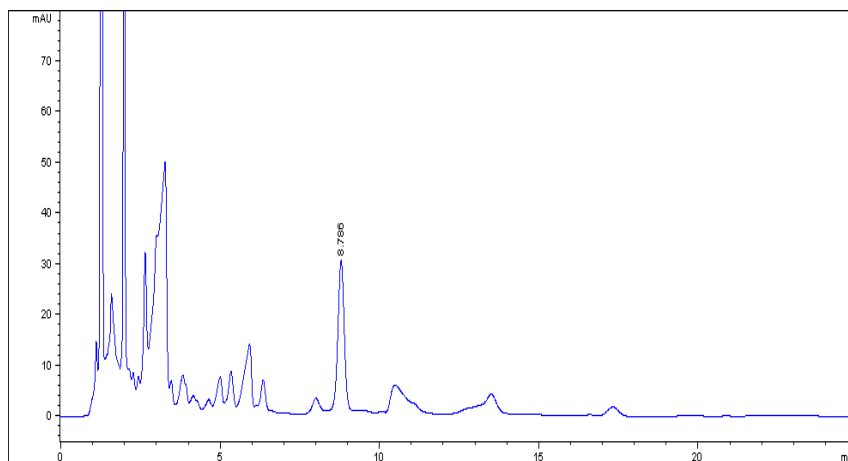
Grind the pills to a fine powder, accurately weigh 1 g in a stoppered conical flask, accurately add 50 mL of 50 % methanol, stopper tightly and weigh. Treat ultrasonically for 20 minutes, allow to cool, weigh again, replenish the lost weight with 50 % methanol, shake well and filter. Accurately measure 10 mL of the filtrate in a 25 mL volumetric flask, dilute with 50 % methanol to volume, shake well, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (11:89)
- Detector wavelength: 238 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide		8.786	29.64	402.4	10013	0.97

# Zhimaikang Capsules (*Zhimaikang Jiaonang*) – 脂脉康胶囊

## Sample source

Commercially available Zhimaikang Capsules

## Chemical reference substances

Puerarin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110752-200209)

## Preparation of test solution

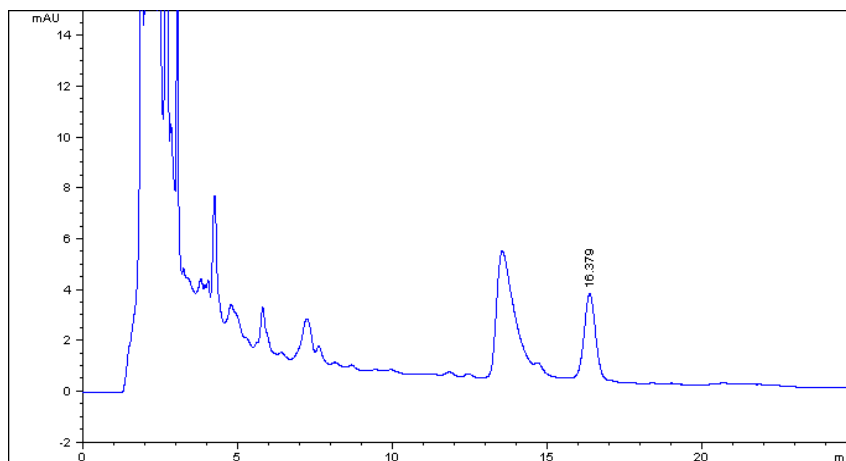
Grind a quantity of the contents to a fine powder, accurately weigh about 0.2 g in a stoppered conical flask, accurately add 50 mL of 30 % ethanol, weigh and treat ultrasonically for 30 minutes, allow to cool, weigh again, replenish the lost weight with 30 % ethanol, mix well and filter through a millipore membrane (0.45  $\mu\text{m}$ ), use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-water (25:75)
- Detector wavelength: 250 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Puerarin	5.552	16.379	3.36	84.2	9859	0.99

# Zhike Juhong Mixture (*Zhike Juhong Koufuye*) – 止咳橘红口服液

## Sample source

Commercially available Zhike Juhong Mixture

## Chemical reference substances

Naringin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110722-200309)

## Preparation of test solution

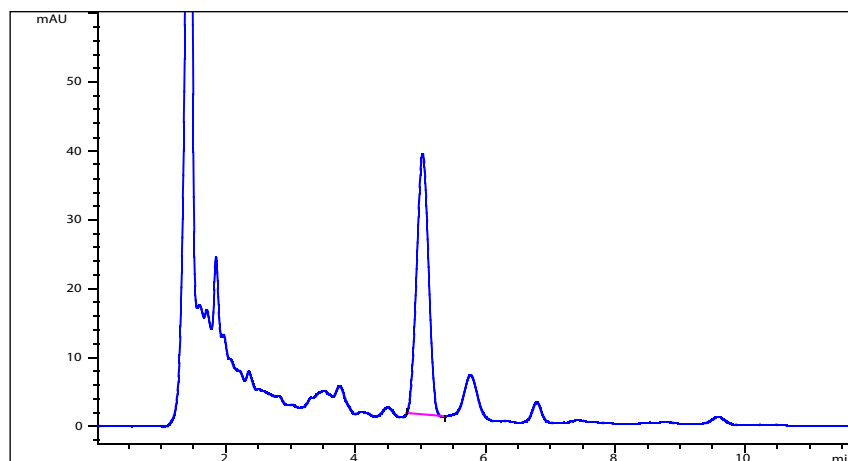
Accurately measure 1 mL of the mixture in a 25 mL volumetric flask, dilute with methanol to volume and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (883975-902)
- Column temperature: 40  $^{\circ}\text{C}$
- Mobile phase: methanol-water-acetic acid (38:62:0.5)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Naringin	3.195	5.034	37.83	478.3	3546	0.98

# Immature Orange Fruit (*Fructus Aurantii Immaturus*) – 枳实

## Sample source

Commercially available Immature Orange Fruit

## Chemical reference substances

Synephrine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110727-200306)

## Preparation of test solution

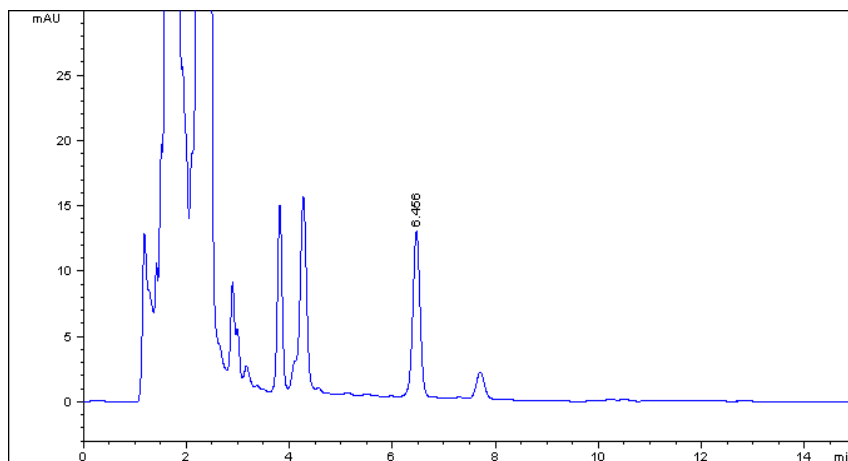
Accurately weigh 1 g of the powder in a stoppered conical flask, add 50 mL of methanol, weigh accurately, heat under reflux for 1.5 hours, allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter. Accurately measure 10 mL of the filtrate and evaporate to dryness. Dissolve the residue in 10 mL of water, mix well, apply to a column (1.5 cm ID) packed with polyamide (60-90 mesh, 2.5 g). Elute with 25 mL of water and collect the eluent, transfer to a 25 mL volumetric flask. Dilute with water to volume and mix well. Filter through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C8, 4.6 $\times$ 150 mm, 5  $\mu\text{m}$  (993967-906)
- Column temperature: 30  $^{\circ}\text{C}$
- Mobile phase: methanol-aqueous mono potassium phosphate solution (0.06 % mono potassium phosphate + 0.1 % sodium dodecyl sulfate + 0.1 % glacial acetic acid) (50:50)
- Detector wavelength: 275 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Synephrine	3.304	6.456	12.60	120.2	10891	0.99

# Zhitong Huazheng Capsules (*Zhitong Huazheng Jiaonang*)

## 止痛化徵胶囊

### Sample source

Commercially available Zhitong Huazheng Capsules

### Chemical reference substances

sodium danshensu (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 110855-200203)

### Preparation of test solution

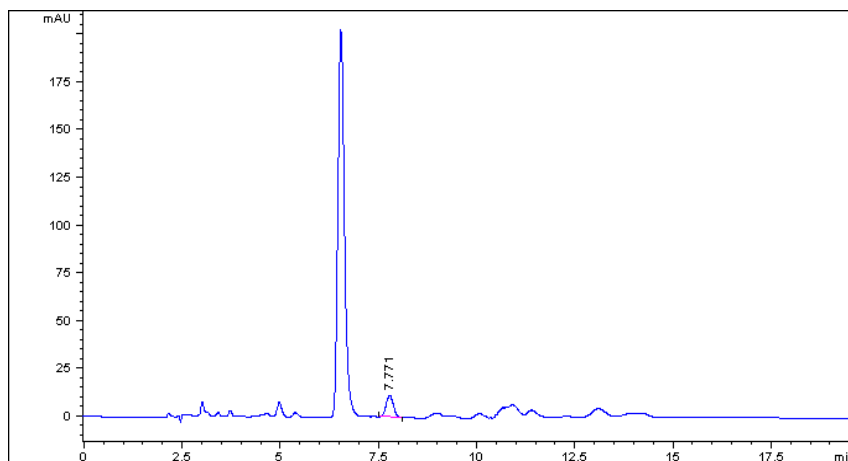
Grind the contents of the capsules to a fine powder, accurately weigh 1 g in a stoppered conical flask, accurately add 50 mL of a solution of hydrochloric acid (1:50), weigh, treat ultrasonically for 30 minutes, allow to cool and weigh again. Replenish the lost weight with a solution of hydrochloric acid (1:50), add 5 g of sodium chloride, stir well and centrifuge. Transfer accurately 25 mL of the supernatant to a separating funnel, extract by shaking with one 50 ml, one 30 ml, and two 20 ml quantities of ethyl acetate. Combine the ethyl acetate extracts, evaporate to dryness on a water bath, dissolve the residue in 50 % methanol, transfer to a 10 mL volumetric flask and dilute to volume and mix well. Filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 30 °C
- Mobile phase: methanol-water-dimethyl- formamide-glacial acetic acid (1:95.5:1: 2.5)
- Detector wavelength: 283 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Danshensu	2.108	7.771	11.54	148.2	8363	1.01

# Prepared Fleeceflower Root (*Radix Polygoni Multiflori Praeparata cum siccp Gucomes Sptae*) – 制何首乌

## Sample source

Commercially available Prepared Fleeceflower Root

## Chemical reference substances

2,3,5,4'-tetrahydroxystibene-2-O-β-D-glucoside (National Institute for the Control of Pharmaceutical and Biological Products, Batch number: 0844-200003)

## Preparation of test solution

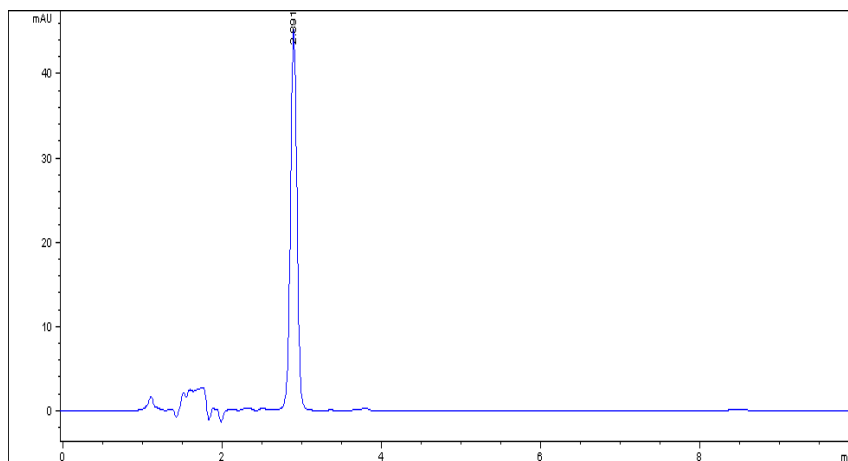
Accurately weigh 0.2 g of the powder in a stoppered conical flask, accurately add 25 mL of dilute ethanol and weigh. Heat under reflux for 30 minutes, allow to cool and weigh again, replenish the lost solvent with dilute ethanol and mix well. Filter the supernatant and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-water (5:15)
- Detector wavelength: 320 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
2,3,5,4'-tetrahydroxystibene-2-O-β-D-glucoside	1.409	2.891	45.10	255.9	6164	1.00

# Glabrous Sarcandra Tablets (*Tabellae Sarcandra glabra*)

肿节风片

## Sample source

Commercially available Glabrous Sarcandra Tablets

## Chemical reference substances

Isofraxidin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0837-200203)

## Preparation of test solution

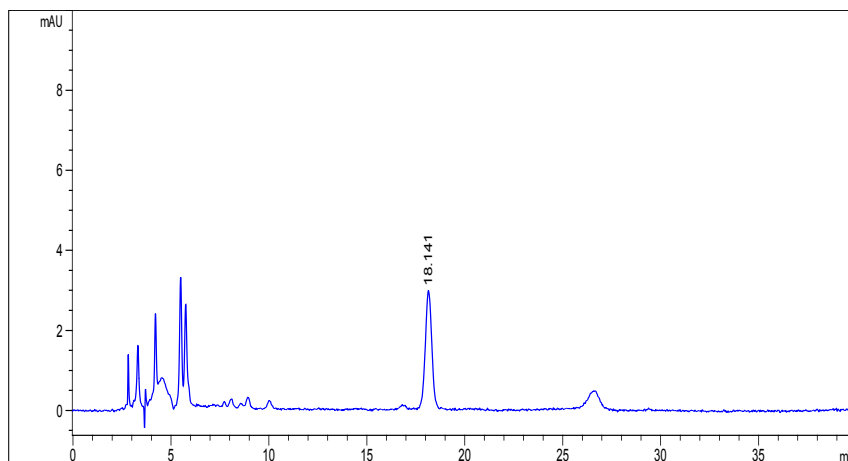
Accurately weigh 10 tablets, remove the coatings and grind to a fine powder, accurately weigh 50 mg of the powder in a stoppered conical flask, accurately add 25 mL of methanol, stopper tightly, weigh and treat ultrasonically for 40 minutes. Allow to cool, weigh again, replenish the lost weight with methanol, mix well and filter, use the filtrate as the test solution.

## Chromatographic conditions

- Column: Agilent TC-C18, 4.6×250 mm, 5 µm (518925-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-0.1 % phosphoric acid (17:83)
- Detector wavelength: 344 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Area (mAU*s)	n	USP T <sub>r</sub>
Isofraxidin	6.256	18.141	69.0	14332	1.02



# Zhonghua Dieda Pills (*Zhonghua Dieda Wan*) – 中华跌打丸

## Sample source

Commercially available Zhonghua Dieda Pills

## Chemical reference substances

Geniposide (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110749-200309)

## Preparation of test solution

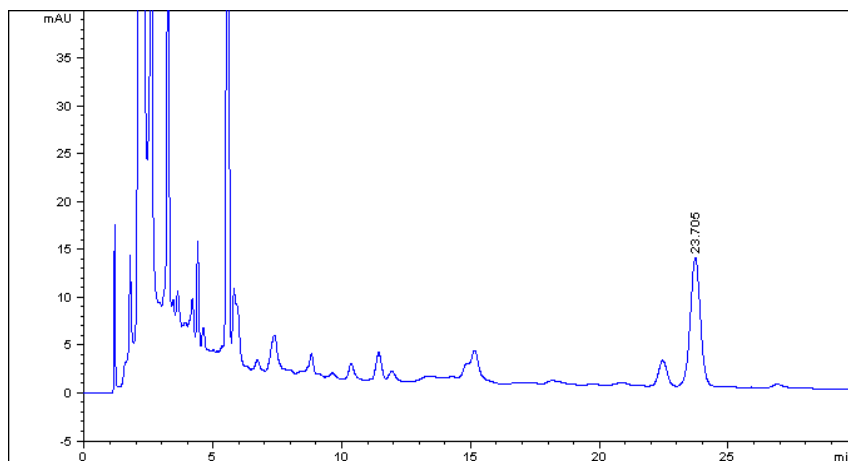
Cut the pills into pieces and accurately weigh 3 g. Accurately add 25 mL of methanol, weigh accurately, heat under reflux on a water bath for 30 minutes, allow to cool, weigh again, and replenish the lost weight with methanol. Shaking thoroughly, filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-water (9:91)
- Detector wavelength: 238nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Geniposide	8.482	23.705	13.40	362.1	18221	1.00

# Zhongfeng Huichun Pills (*Zhongfeng Huichun Wan*) – 中风回春丸

## Sample source

Commercially available Zhongfeng Huichun Pills

## Chemical reference substances

Sodium danshensu (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110855-200203)

## Preparation of test solution

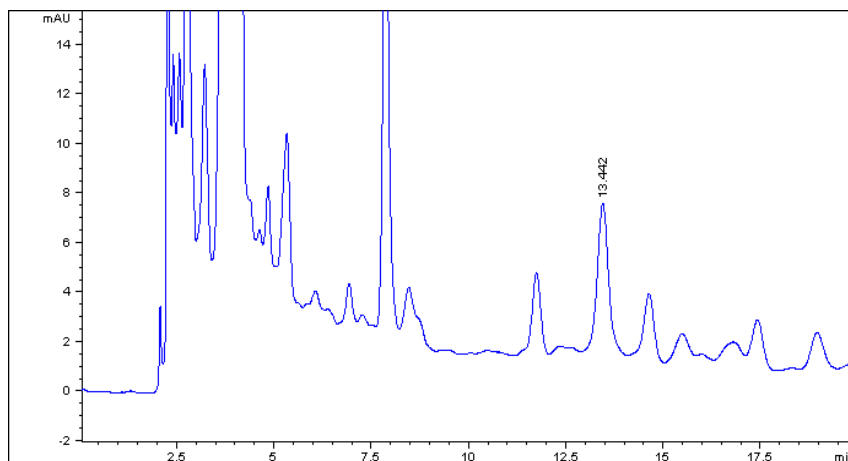
Grind a quantity of pills to a fine powder, accurately weigh 0.4 g of the powder in a stoppered conical flask, accurately add 25 mL of 50 % methanol, stopper tightly, weigh, treat ultrasonically for 30 minutes, allow to cool, replenish the lost weight with 50 % methanol, shake well, centrifuge, filter the supernatant through a millipore membrane (0.45  $\mu\text{m}$ ) and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6 $\times$ 250 mm, 5  $\mu\text{m}$  (880975-902)
- Column temperature: 25  $^{\circ}\text{C}$
- Mobile phase: methanol-1.5 % glacial acetic acid (4.5:95.5)
- Detector wavelength: 280 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu\text{L}$

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Danshensu	4.335	13.338	6.09	124.8	10951	0.95

# Shuanghuanglian Injection (*Zhusheyong Shuanghuanglian*)

## 注射用双黄连（冻干）

### Sample source

Commercially available Shuanghuanglian for Injection

### Chemical reference substances

Baicalin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110715-200212)

### Preparation of test solution

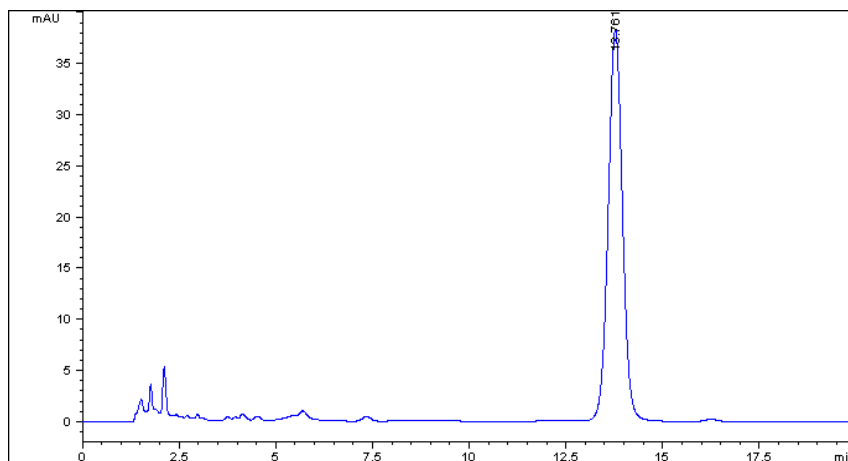
Accurately weight 10 mg of the contents, add a quantity of 50 % methanol, treat ultrasonically for 20 minutes to dissolve. This gives a solution containing about 0.2 mg/mL as the test solution.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-0.15 % glacial acetic acid (24.8:75.2)
- Detector wavelength: 278nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Baicalin	8.174	13.761	38.12	968.8	7137	1.02

# Shuanghuanglian Injection (*Zhusheyong Shuanghuanglian*)

## 注射用双黄连（冻干）

### Sample source

Commercially available Shuanghuanglian for Injection

### Chemical reference substances

Forsythin (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110821-200305)

### Preparation of test solution

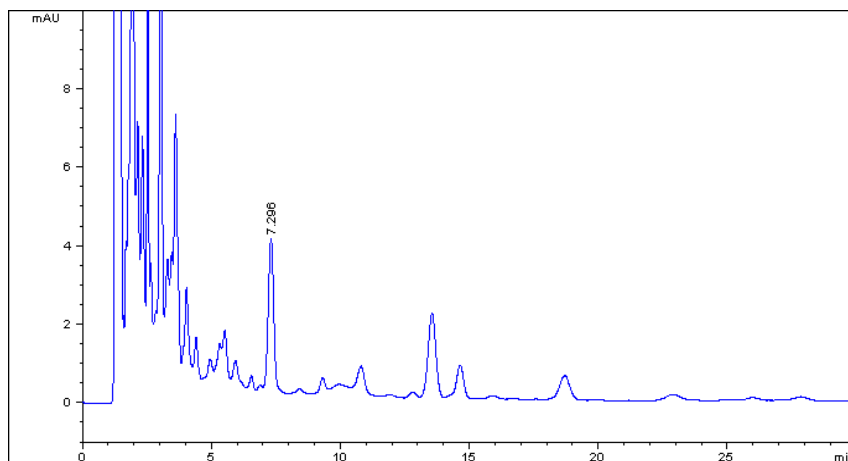
Accurately weigh 0.1 g, dissolve in 5 mL of a 65 % solution of ethanol, apply to a column (1 cm in inner diameter), packed with neutral alumina (100-200 mesh, 5 g), elute with 65 % ethanol, collect the eluent in a 25 mL volumetric flask, dilute with 65 % ethanol to volume and mix well.

### Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 25 °C
- Mobile phase: acetonitrile-0.05 % phosphoric acid (19.5:80.5)
- Detector wavelength: 203 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Forsythin	3.864	7.296	3.83	54.9	5916	0.97

# Shuanghuanglian Injection (*Zhusheyong Shuanghuanglian*)

## 注射用双黄连（冻干）

### Sample source

Commercially available Shuanghuanglian for Injection

### Chemical reference substances

Chlorogenic acid (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110753-200212)

### Preparation of test solution

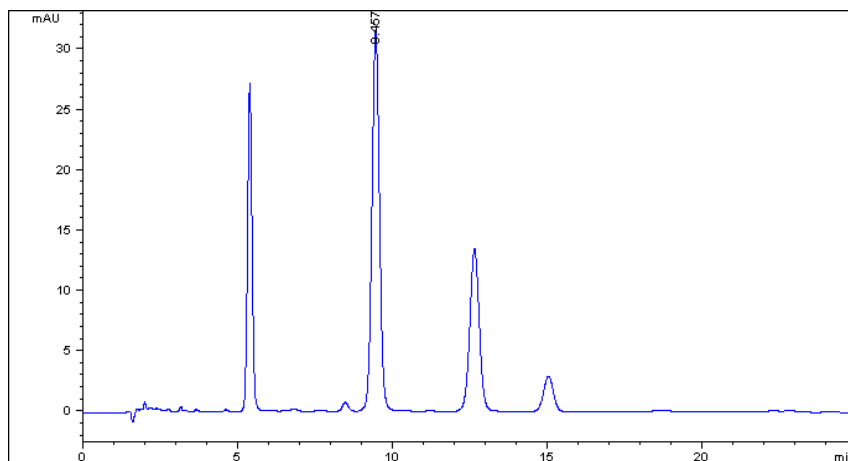
Accurately weigh 60 mg in a 50 mL amber volumetric flask, dissolve and dilute to volume with water, and mix well.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (containing 1.2 % glacial acetic acid and 0.25 % triethylamine (24.8:75.2))
- Detector wavelength: 324 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Chlorogenic acid	5.305	9.457	31.55	532.0	7632	1.02

# Zhuanggu Shenjin Capsules (*Zhuanggu Shenjin Jiaonang*)

## 壮骨伸筋胶囊

### Sample source

Commercially available Zhuanggu Shenjin Capsules

### Chemical reference substances

Icariine (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 0737-9910)

### Preparation of test solution

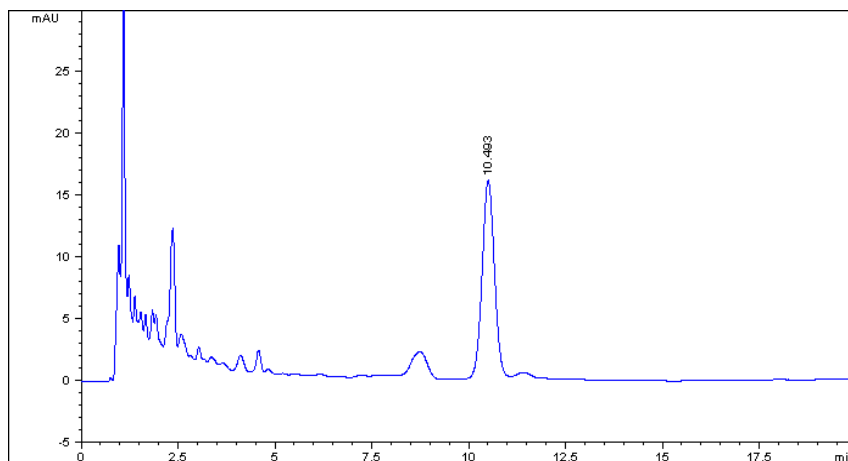
Grind the contents of the capsules to a fine powder and mix well. Accurately weigh 0.5 g of the powder in a Soxhlet extractor, heat under reflux with 40 mL of chloroform for 2 hours, discard the chloroform solution. Evaporate the residue to dryness, add 40 mL of methanol, heat under reflux for 4 hours. Evaporate the extract, moisten the residue with a quantity of methanol, dissolve in 2 mL of water, apply to a column of macroporous absorbency resins D101, elute with 100 mL of water, 100 mL of 30 % ethanol and 50 mL of 70 % ethanol at the speed of 3 mL/min. Collect the eluent of 70 % ethanol and evaporate to dryness. Dissolve the residue in methanol in a 5 mL volumetric flask and dilute to volume, mix well.

### Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 μm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (54:46)
- Detector wavelength: 270 nm
- Flow rate: 1.0 mL/min
- Injection volume: 2 μL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Icariine	5.996	10.493	16.05	355.2	5285	1.03

# Tatarian Aster Root (*Radix et Rhizoma Asteris*) – 紫菀

## Sample source

Commercially available Tatarian Aster Root

## Chemical reference substances

Shionone (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 111581-200403)

## Preparation of test solution

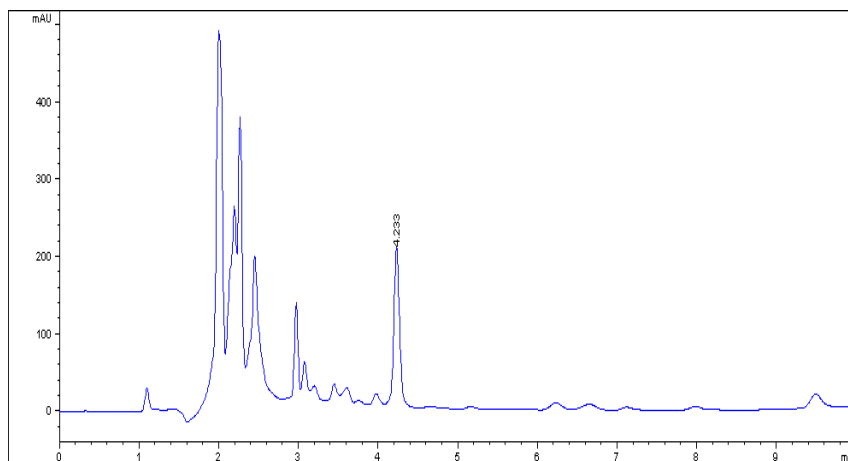
Accurately weigh 1 g of the powder in a stoppered conical flask, accurately add 20 mL of methanol and weigh. Allow to soak for 1 hour at 40 °C, treat ultrasonically for 15 minutes, allow to cool and weigh again, replenish the lost solvent with methanol and mix well.

## Chromatographic conditions

- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-water (13:87)
- Detector wavelength: 200 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Shionone	0.693	4.233	197.39	978.1	17985	1.05

# Zuojin Pills (*Zuojin Wan*) – 左金丸

## Sample source

Commercially available Zuojin Pills

## Chemical reference substances

Berberine hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products, Batch number 110713-200209)

## Preparation of test solution

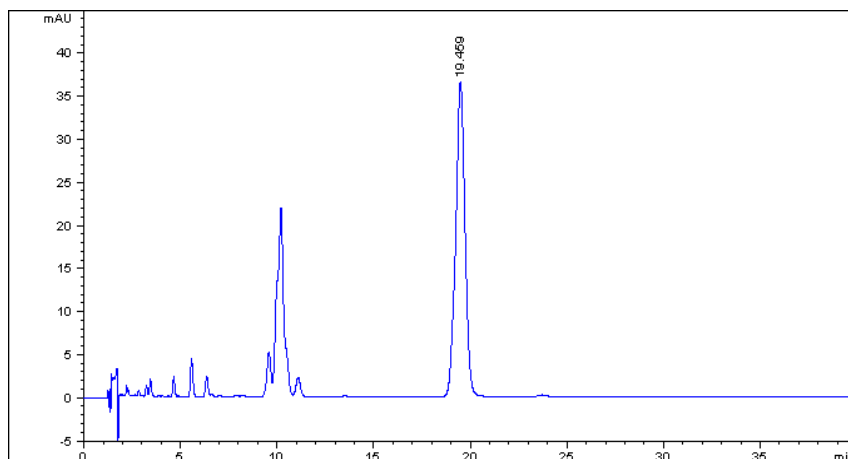
Grind a quantity of the pills to a fine powder, accurately weigh 1.0 g in a stoppered conical flask, accurately add 100 mL of a mixture of hydrochloric acid and methanol (1:100) and weigh. Allow to soak for 1 hour and then heat under reflux for 1 hour, allow to cool, weigh again, replenish the lost weight with a mixture of hydrochloric acid and methanol (1:100) and shake well. Filter and use the filtrate as the test solution.

## Chromatographic conditions

- Column: ZORBAX XDB C18, 4.6×150 mm, 5 µm (993967-902)
- Column temperature: 40 °C
- Mobile phase: acetonitrile-0.05 mol/L potassium dihydrogen phosphate (adjust pH with phosphoric acid to 3.06) (20:80)
- Detector wavelength: 350 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series diode-array detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T <sub>r</sub>
Berberine		19.459	36.34	1212.1	8504	0.98





## **Chemical Drugs**



# Amoxicillin – 阿莫西林

Amoxicillin (130409-200208) – Method number WR048

## Assay

Test solution: dissolve a quantity of the substance being examined, accurately weighed, in mobile phase A to produce a solution of 600 µg/mL, mix well and use as the test solution.

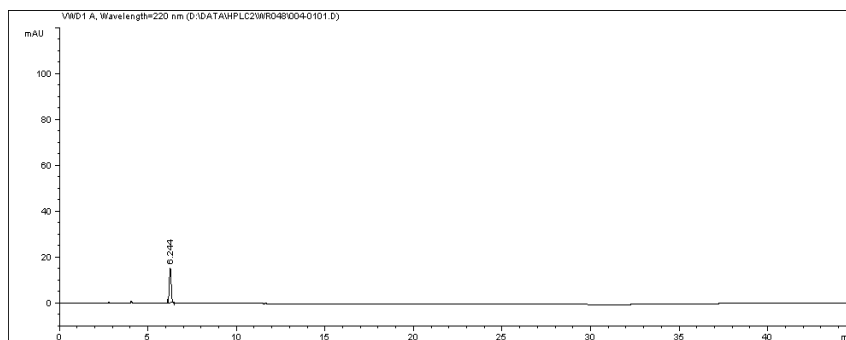
Reference solution: dissolve a quantity of amoxicillin CRS, accurately weighed, in mobile phase A to produce a solution of 6 µg/mL, mix well and use as the reference solution.

## Chromatographic conditions

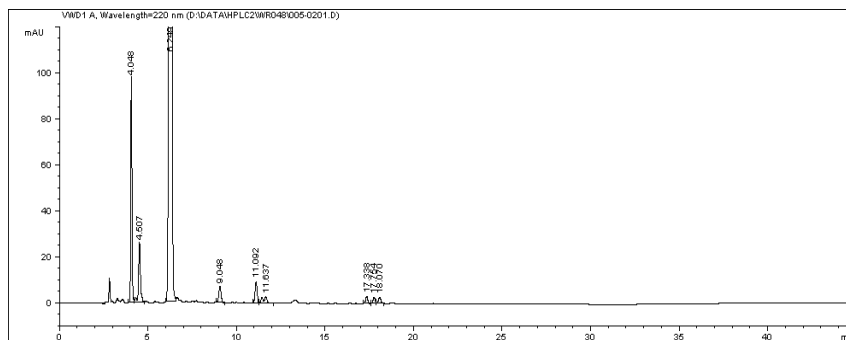
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm, (880975-914)
- Mobile phase: A (0.05 M potassium dihydrogen phosphate (pH 5.0)-ACN=99:1) B (0.05 M potassium dihydrogen phosphate (pH 5.0)-ACN=80:20) 0 min, 97.5 %A; 15 min, 85 %A; 25 min, 85 %A; 30 min, 97.5 %A; 45 min, 97.5 %A
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WR048\004-0101



The chromatogram of the test solution---HPLC2\WR048\005-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Amoxicillin	6.25	10410.5	16988	9.7	0.99
Impurity1	4.05	478.3	16039	/	1.10
Impurity2	4.51	190.6	11555	3.1	/
Impurity3	9.05	63.3	24558	13.2	0.96
Impurity4	11.09	77.7	41992	9.1	0.99

# Amoxicillin Capsules – 阿莫西林胶囊

## Amoxicillin (130409-200208) – Method number WR051

### Assay

Test solution: Dissolve an accurately weighed quantity of the mixed contents in mobile phase A to produce a solution of 600 µg of amoxicillin per mL, mix well and filter, use the filtrate as the test solution.

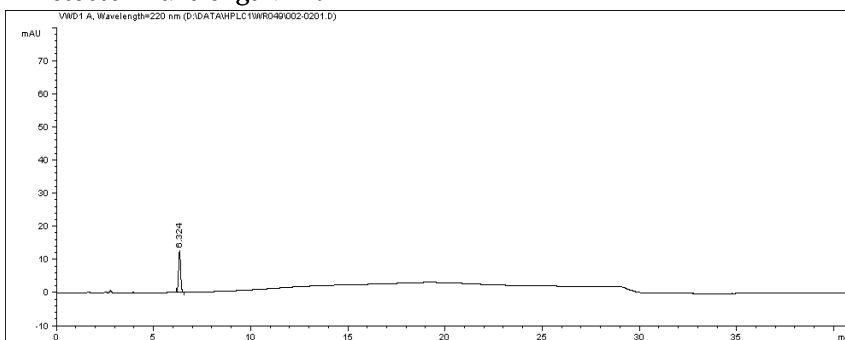
Reference solution: Dissolve a quantity of amoxicillin CRS, accurately weighed, in mobile phase A to produce a solution of 6 µg/mL, mix well and use as the reference solution.

### Chromatographic conditions

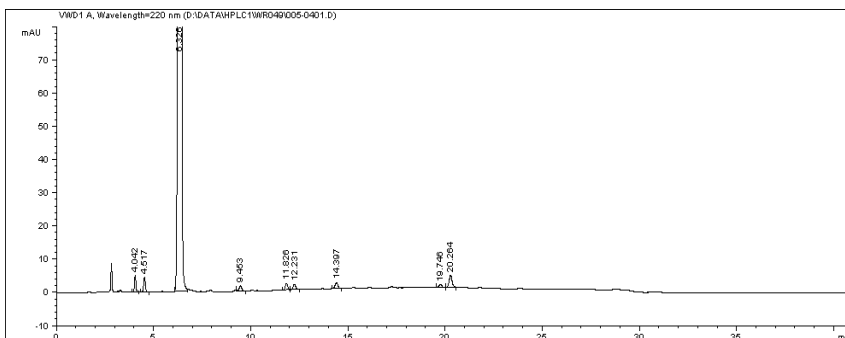
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm, (880975-914)
- Mobile phase: A (pH 5.0 potassium dihydrogen phosphate/acetonitrile=99:1) B (pH 5.0 potassium dihydrogen phosphate/acetonitrile=80:20) 0 min, 97.5 %A; 15 min, 85 %A; 25 min, 85 %A; 30 min, 97.5 %A; 45 min, 97.5 %A
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR049\002-0201.D



The chromatogram of the test solution--- HPLC1\WR049\005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Amoxicillin	6.33	8781.6	16339	10.0	0.99
Impurity1	4.04	26.3	14642	/	1.00
Impurity2	4.52	28.5	11997	3.2	1.02
Impurity3	20.26	40.1	83548	21.5	1.12

# Amoxicillin and Clavulanate Potassium Tablets

Amoxicillin (130409-200208) Clavulanic acid (130429-200203) – Method number WA087  
阿莫西林克拉维酸钾片片

## Assay

Test solution: Grind 10 tablets to a fine powder, dissolve an accurately weighed quantity of the powdered tablets (equivalent to about the average weight of one tablet) in water in a 200 mL volumetric flask, dilute to volume, mix well and filter. Transfer 2 mL of the filtrate, accurately measured, to a 10 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

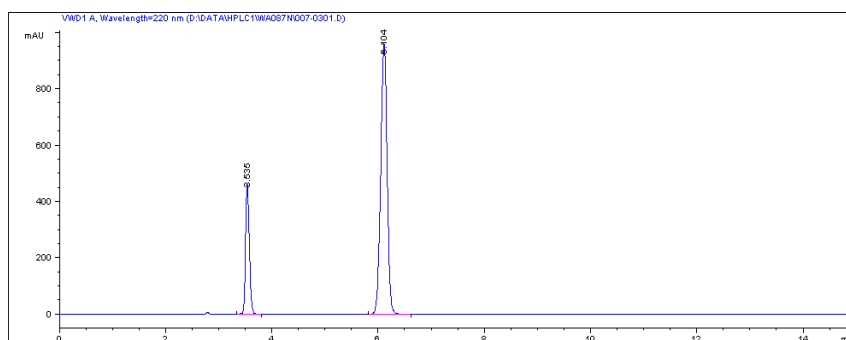
Reference solution: Dissolve a quantity of amoxicillin CRS and clavulanic acid CRS in water and use as the reference solution. The concentration should be equivalent to the test solution.

## Chromatographic conditions

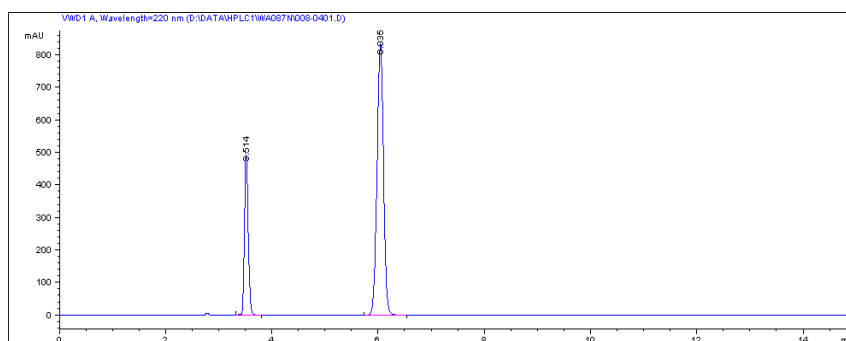
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.01 mol/L potassium dihydrogen phosphate solution (pH=6.0):acetonitrile =96:4
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA087\N007-0301



The chromatogram of the test solution --- HPLC1\ WA087\N008-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clavulanic acid	3.51	2459.7	10995	/	1.15
Amoxicillin	6.04	7068.5	11750	14.1	1.00

# Amoxicillin and Clavulanate Potassium Tablets

Amoxicillin (130409-200208) Clavulanic acid (130429-200203) – Method number WA087  
阿莫西林克拉维酸钾片片

## Assay

Test solution: Grind 10 tablets to a fine powder, dissolve an accurately weighed quantity of the powdered tablets in mobile phase A to produce a solution of 2 mg of amoxicillin per mL, mix well and filter. Use the filtrate as the test solution.

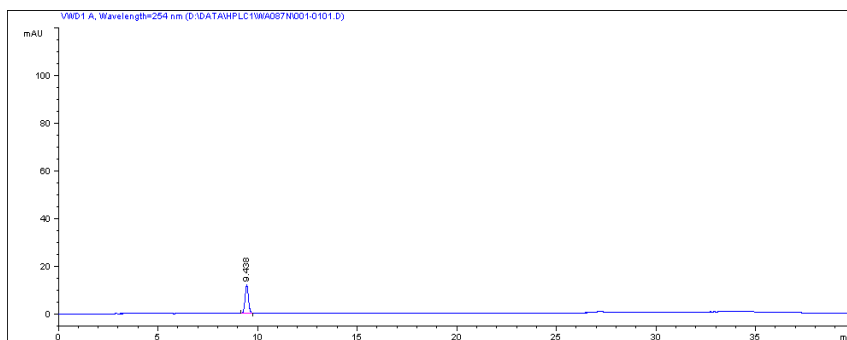
Reference solution: Dissolve a quantity of amoxicillin CRS in mobile phase to produce a solution of 40 µg/mL mix well and use as the reference solution.

## Chromatographic conditions

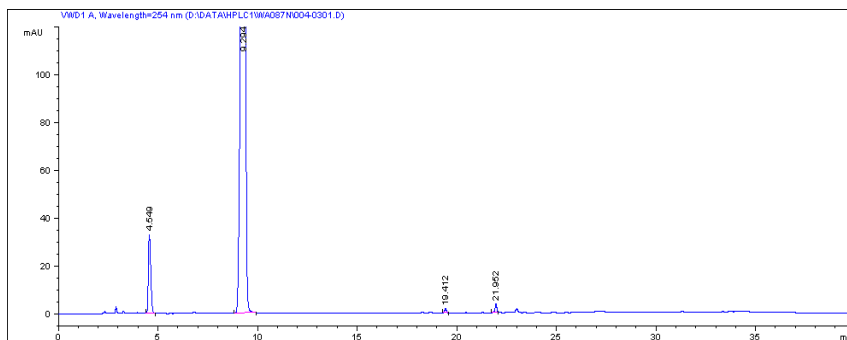
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: A: 0.01 mol/L potassium dihydrogen phosphate (pH=6.0); B: acetonitrile: A (80:20)
- Elution gradient: 0 min, 0 % B; 1 min, 2 % B; 9 min, 2 % B; 30.5 min, 41 % B; 32 min, 2 % B; 35 min, 0 % B; 40 min, 0 % B.
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA087\N001-0101



The chromatogram of the test solution --- HPLC2\WA087\N004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clavulanic acid	4.56	284.2	6097	/	1.19
Amoxicillin	9.27	5896.6	10685	15.9	0.85

# Amoxicillin Sodium – 阿莫西林钠

## Amoxicillin (130409-200208) – Method number WR050

### Assay

Test solution: Dissolve an accurately weighed quantity in mobile phase to produce a solution of 0.2 mg/mL and use as the test solution.

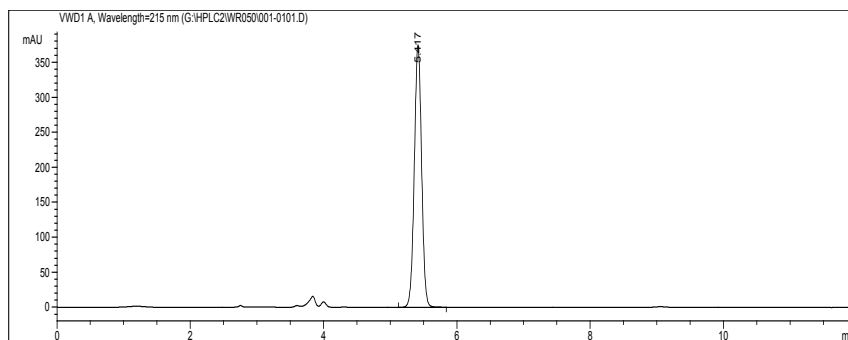
Reference solution: Dissolve an accurately weighed quantity of amoxicillin CRS in mobile phase to produce a solution of 0.2 mg/mL and use as the reference solution.

### Chromatographic conditions

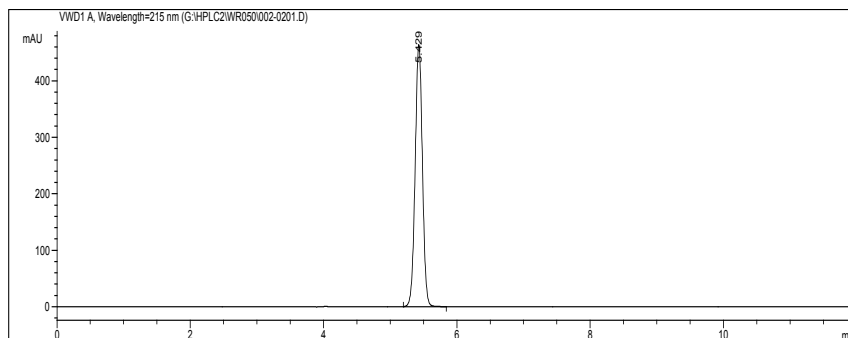
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 μm (880975-914)
- Mobile phase: 0.05M potassium dihydrogen phosphate(pH=5.0): acetonitrile= 96:4
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 215 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR050001-0101



The chromatogram of the test solution---HPLC2WR050002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Amoxicillin	5.43	3510.2	11393	/	1.01



# Amoxicillin Tablets – 阿莫西林片

## Amoxicillin (130409-200208) – Method number WR049

### Assay

Test solution: Grind 10 tablets to a fine powder. Dissolve a quantity of powdered tablets, accurately weighed, in mobile phase A to produce a solution of 600 µg/mL, mix well and filter, use the filtrate as the test solution.

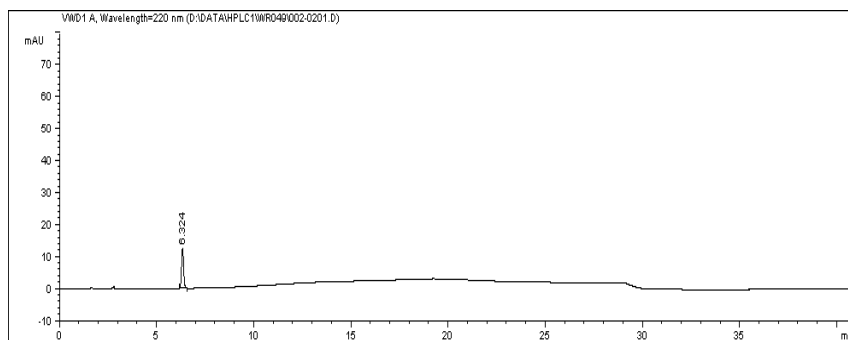
Reference solution: Dissolve an accurately weighed quantity of amoxicillin CRS in mobile phase A to produce a solution of 6 µg/mL, mix well and use as the reference solution.

### Chromatographic conditions

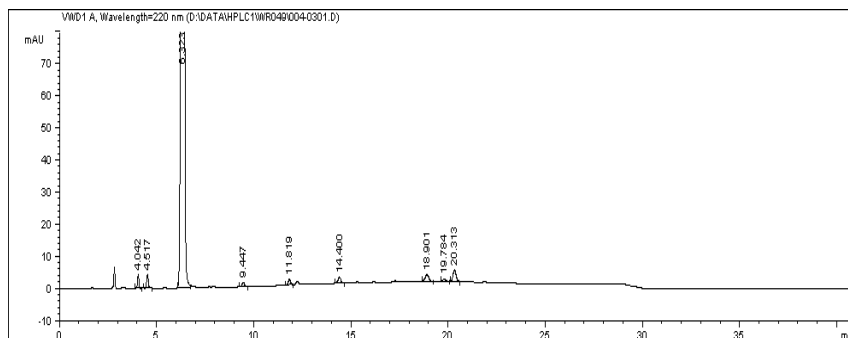
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: A (pH 5.0 M potassium dihydrogen phosphate -ACN=99:1) B (pH 5.0 M potassium dihydrogen phosphate -ACN=80:20) 0 min, 97.5 %A; 15 min, 85 %A; 25 min, 85 %A; 30 min, 97.5 %A; 45 min, 97.5 %A
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR049\002-0201.D



The chromatogram of the test solution--- HPLC2\WR049\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Amoxicillin	6.32	8819.5	16789	10.0	0.99
Impurity1	4.04	21.5	15009	/	1.00
Impurity2	4.52	27.6	12300	3.2	1.03
Impurity3	18.90	30.1	52512	15.0	1.17
Impurity4	20.3	42.5	79220	1.8	1.14

# Aspirin Enteric-microencapsulated Capsules – 阿司匹林肠溶胶囊

## Aspirin (100113-200302) Salicylic acid (100106-200303) – Method number WA080

### Assay

**Test solution:** Dissolve an accurately weighed quantity (equivalent to about 0.1 g of aspirin) in a solution of 1 % glacial acetic acid in anhydrous methanol in a 100 mL volumetric flask and dilute to volume, mix well and filter. Transfer 5 mL of the filtrate to a 100 mL volumetric flask and dilute with a solution of 1% glacial acetic acid in anhydrous methanol to volume, mix well and use as the test solution.

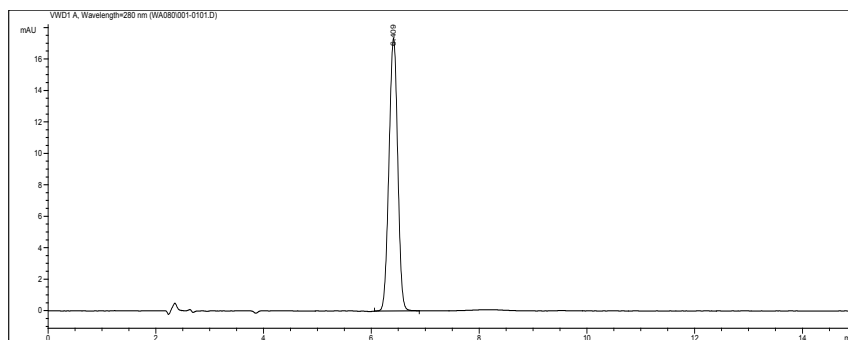
**Reference solution:** Dissolve and dilute an accurately weighed quantity of aspirin CRS in a solution of 1 % glacial acetic acid in anhydrous methanol to produce a solution of 50 µg/mL and use as the reference solution.

### Chromatographic conditions

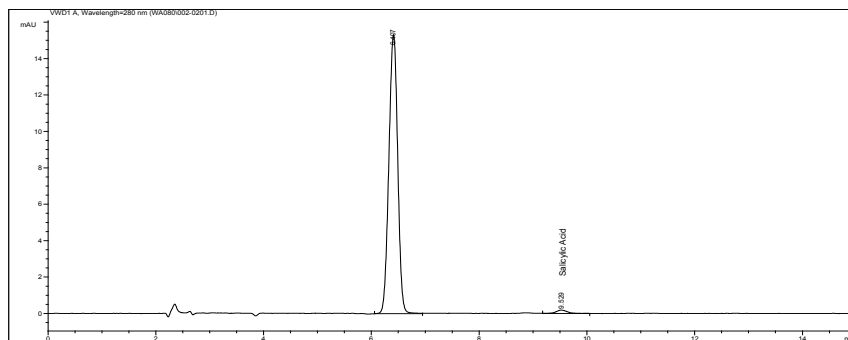
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 1 % glacial acetic acid solution : methanol = 55:45
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC\WA080\00-0101



The chromatogram of the test solution --- HPLC\WA080\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aspirin	6.41	173.9	7249	/	0.99
Salicylic acid	9.53	2.3	11543	9.5	1.07

# Aspirin Enteric-Microencapsulated Capsules – 阿司匹林肠溶胶囊

## Aspirin (100113-200302) Salicylic acid (100106-200303) – Method number WA080

### Assay

**Test solution:** Accurately weigh a quantity of the contents, equivalent to about 0.1 g of aspirin, in a 100 mL volumetric flask, dilute with a solution of 1 % glacial acetic acid in anhydrous methanol to volume, mix well and filter. Use the filtrate as the test solution.

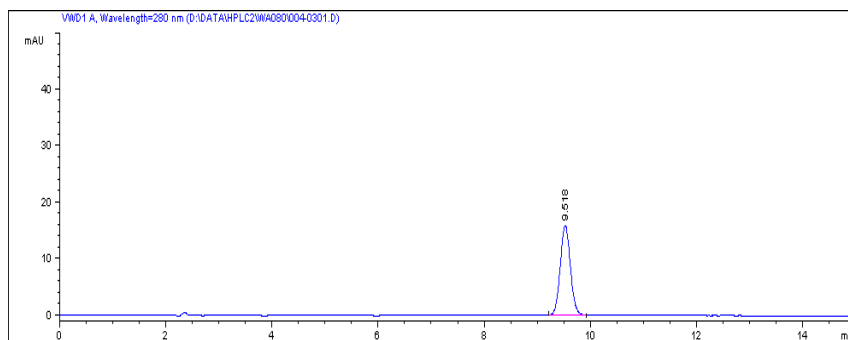
**Reference solution:** Dissolve an accurately weighed quantity of salicylic acid CRS with in a solution of 1 % glacial acetic acid in anhydrous methanol to produce a solution of 30 µg/mL and use as the reference solution.

### Chromatographic conditions

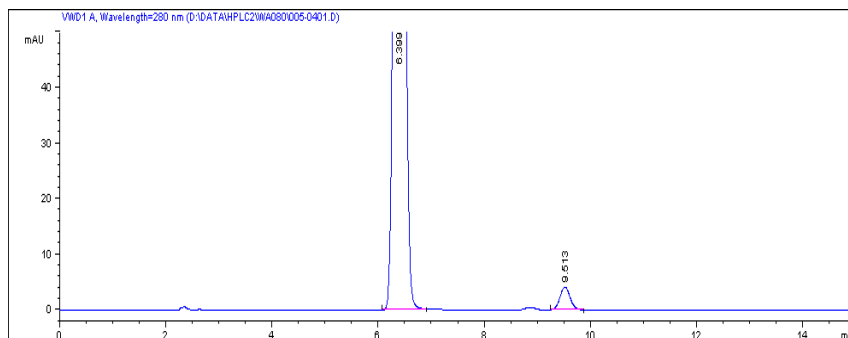
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 1 % glacial acetic acid solution : methanol = 55:45
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA080\004-0301



The chromatogram of the test solution --- HPLC2\WA080\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Aspirin	6.41	173.9	7249	/	0.99
Salicylic acid	9.53	2.3	11543	9.5	1.07

# Aspirin Effervescent Tablets – 阿司匹林泡腾片

Aspirin (100113-200302) – Method number WA268

## Assay

**Test solution:** Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder equivalent to about 25 mg of aspirin in a 100 mL volumetric flask, add 50 mL of a mixture of acetonitrile-methanol-formic acid (40:59:1), treat ultrasonically to dissolve the aspirin, mix well, filter and use as the test solution.

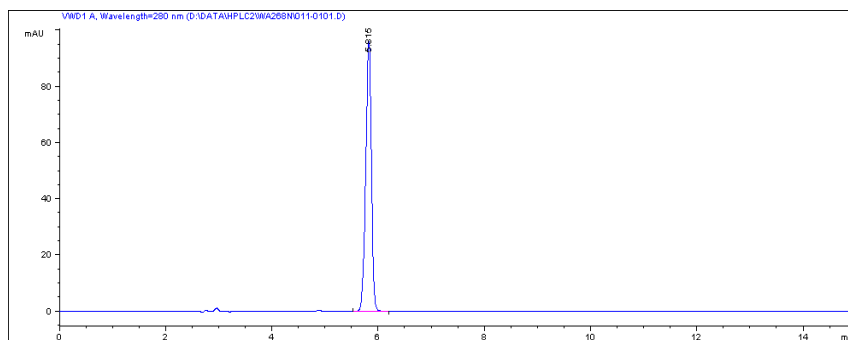
**Reference solution:** Dissolve an accurately weighed quantity of aspirin CRS in a mixture of acetonitrile-methanol-formic acid (40:59:1) to produce the solution of 0.5 mg/mL and use as the reference solution.

## Chromatographic conditions

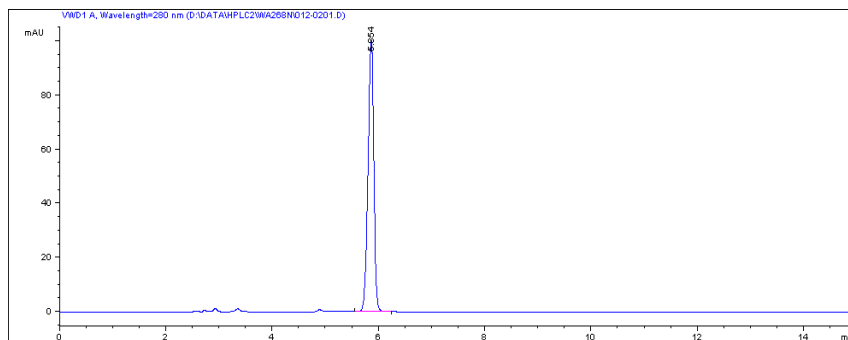
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile: methanol: 0.01 mol/L potassium dihydrogen phosphate (containing 0.275 % of triethylamine) (adjust pH to 3.3 with phosphoric acid) =10:30:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA268N011-0101



The chromatogram of the test solution--- HPLC2WA268N012-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Aspirin	5.85	755.4	12561	/	0.95

# Aspirin Effervescent Tablets – 阿司匹林泡腾片

Aspirin (100113-200302) – Method number WA268

## Assay

**Test solution:** Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder equivalent to about 25 mg of aspirin in a 100 mL volumetric flask, add 50 mL of a mixture of acetonitrile-methanol-formic acid (40:59:1), treat ultrasonically to dissolve the aspirin, mix well, filter and use as the test solution.

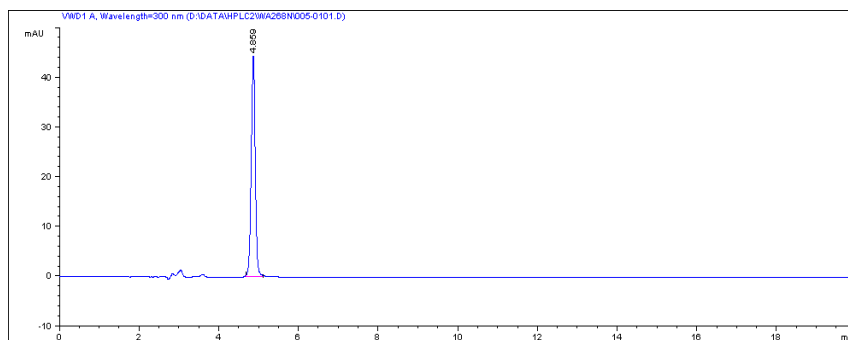
**Reference solution:** Dissolve an accurately weighed quantity of aspirin CRS in a mixture of acetonitrile-methanol-formic acid (40:59:1) to produce the solution of 15 µg/mL and use as the reference solution.

## Chromatographic conditions

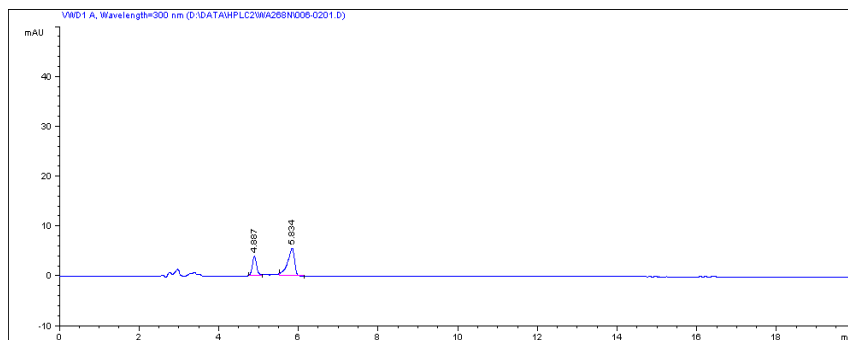
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile: methanol: 0.01 mol/L potassium dihydrogen phosphate (containing 0.275 % of triethylamine) (adjust pH to 3.3 with phosphoric acid) =10:30:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA268N005-0101



The chromatogram of the test solution--- HPLC2WA268N006-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aspirin	5.83	69.7	5744	3.9	0.71
Salicylic acid	4.89	27.0	11348	/	1.16

# Sodium Ferulate – 阿魏酸钠

## Sodium Ferulate – Method number WA088

### Assay

Test solution: Dissolve a quantity of the substance being examined in mobile phase to produce a solution of 0.7 mg/mL and use as the test solution.

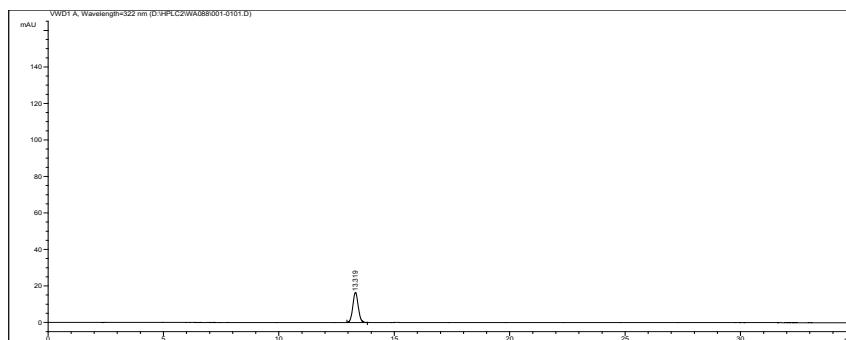
Reference solution: Dilute an accurately measured quantity of test solution with mobile phase to produce a solution of 7 µg/mL and use as the reference solution.

### Chromatographic conditions

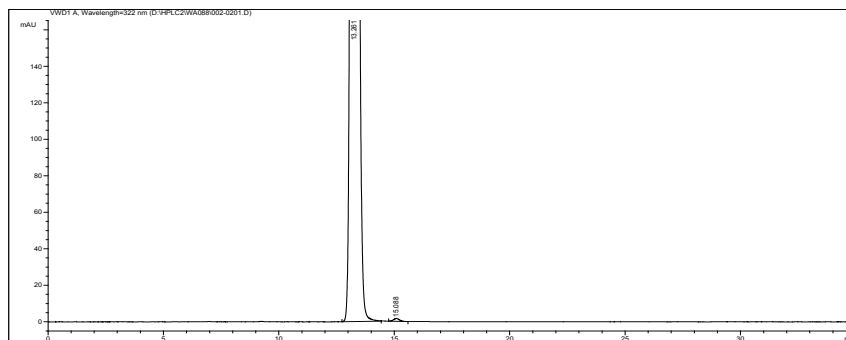
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water : methanol : acetic acid = 69:30:1.5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 322 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA088\001-0101



The chromatogram of the test solution--- HPLC2\WA088\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Sodium Ferulate	13.26	27443.3	15295	/	1.14
Impurity	15.09	26.7	17383	4.1	0.90

# Aciclovir – 阿昔洛韦

Aciclovir (630-200001) – Method number WA160

## Assay

**Test solution:** Dissolve about 50 mg, accurately weighed, in 5 mL of 0.4 % sodium hydroxide solution in a 250 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

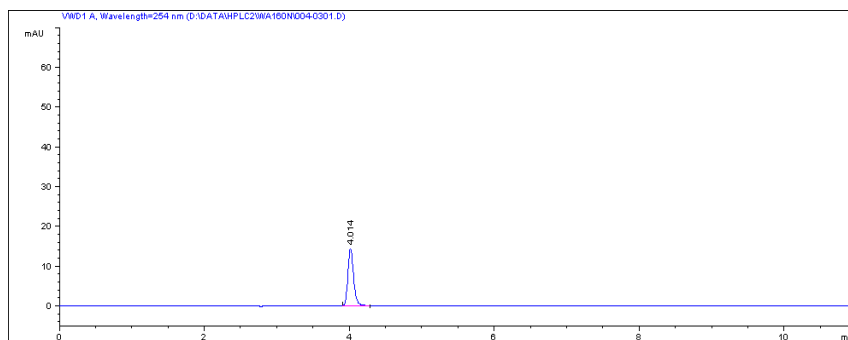
**Reference solution:** Dissolve 10 mg of guanine CRS in a 0.4 % sodium hydroxide solution in a 100 mL volumetric flask, dilute to volume and mix well. Measure accurately 2 mL in a 100 mL volumetric flask, dilute to volume with water, mix well and use as the reference solution.

## Chromatographic conditions

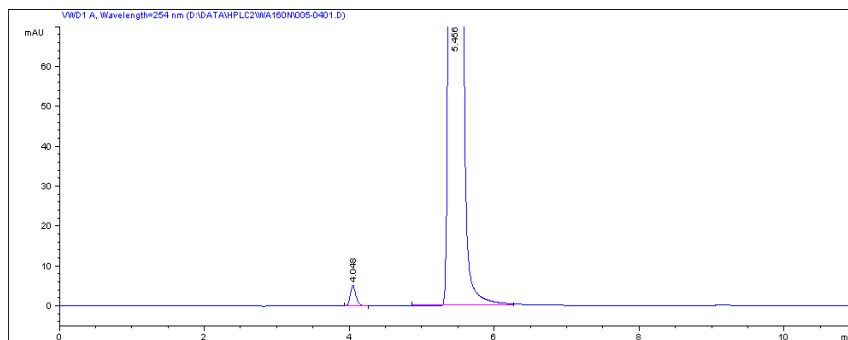
- Column : Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA160N004-0301



The chromatogram of the test solution--- HPLC2\ WA160N005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Guanine	4.05	27.4	13983	/	1.22
Aciclovir	5.46	7040.4	15143	8.9	1.12

# Aciclovir Eye Drops – 阿昔洛韦滴眼液

Aciclovir (140630-200001) – Method number WA085

## Assay

Test solution: Dilute an accurately measured quantity with water to produce a solution of 20 µg/mL, mix well.

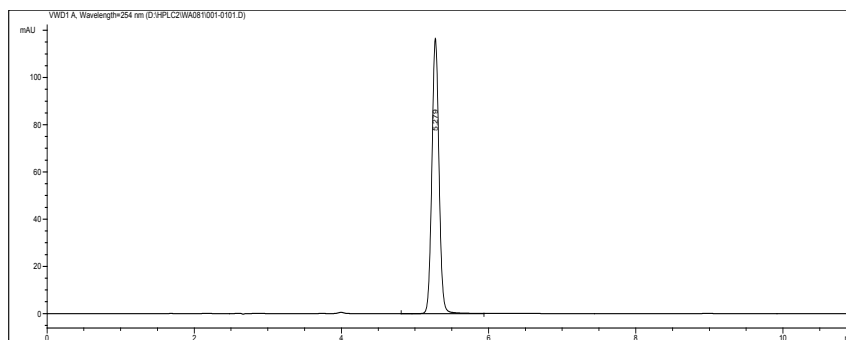
Reference solution: Repeat the procedure, using aciclovir CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

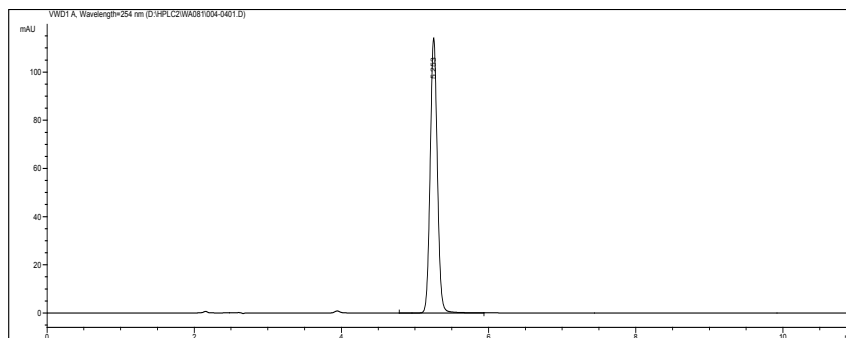
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 10 : 90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA081\001-0101



The chromatogram of the test solution--- HPLC2\ WA081\004-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.26	763.1	14727	/	1.05



# Aciclovir Eye Drops – 阿昔洛韦滴眼液

Aciclovir (140630-200001) – Method number WA085

## Assay

Test solution: Dilute an accurately measured quantity with water to produce a solution of 200 µg/mL as the test solution.

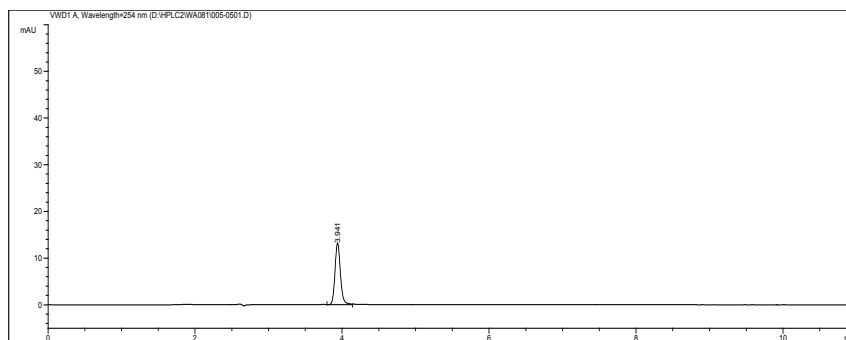
Reference solution: Dissolve 10 mg of guanine CRS in a quantity of 0.4 % sodium hydroxide solution in a 100 mL volumetric flask, dilute with water to volume and mix well. Dilute an accurately measured quantity with water to produce a solution of 2 mg/mL as the reference solution.

## Chromatographic conditions

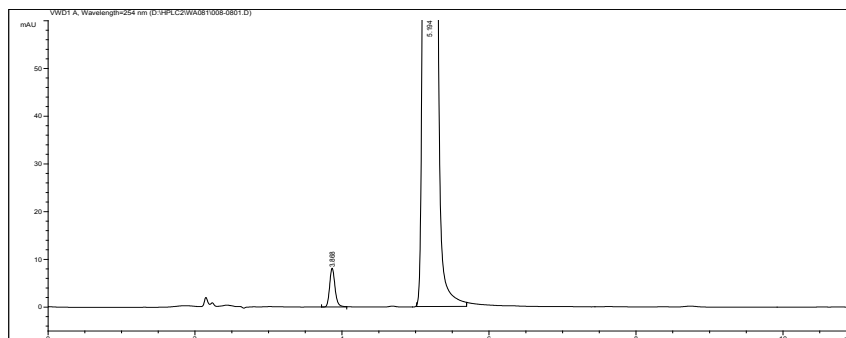
- Column : Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of guanine---HPLC2\WA081\005-0501



The chromatogram of the test solution--- HPLC2\WA081\008-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Guanine	3.87	41.4	14097	/	1.17
Aciclovir	5.19	7375.4	13944	8.6	1.06

# Aciclovir Capsules – 阿昔洛韦胶囊

Aciclovir (630-200001) – Method number WA084

## Assay

Test solution: Accurately weigh a quantity of the powdered, well-mixed contents, equivalent to about 50 mg of aciclovir in a 250 mL volumetric flask, add 5 mL of 0.4 % sodium hydroxide solution and treat ultrasonically for 1 minute, add a quantity of water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Dilute an accurately measured quantity of the filtrate with water to produce a solution of 20 µg/mL and use as the test solution.

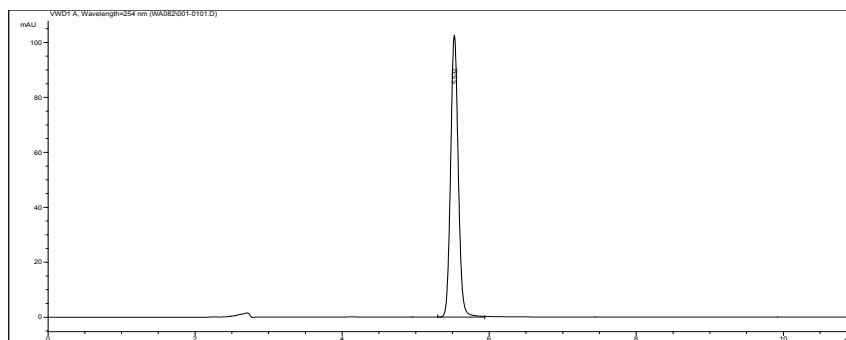
Reference solution: Repeat the procedure, using aciclovir CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

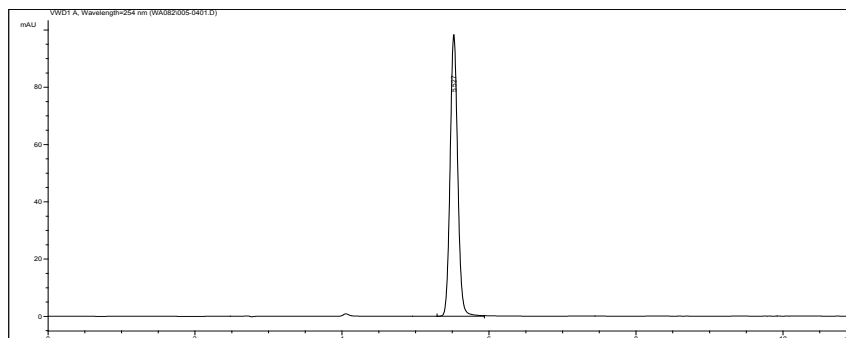
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA08Z001-0101



The chromatogram of the test solution--- HPLC2WA08Z005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.52	703.7	14165	/	1.06

# Aciclovir Chewable Tablets – 阿昔洛韦咀嚼片

Aciclovir (140630-200001) – Method number WA082

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 mg of acyclovir, in a 250 mL volumetric flask, add 5 mL of 0.4 % sodium hydroxide solution and treat ultrasonically for 1 minute, add a quantity of water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Dilute a quantity of the filtrate, accurately measured, with water to produce a solution containing about 20 µg/mL, mix well and use as the test solution.

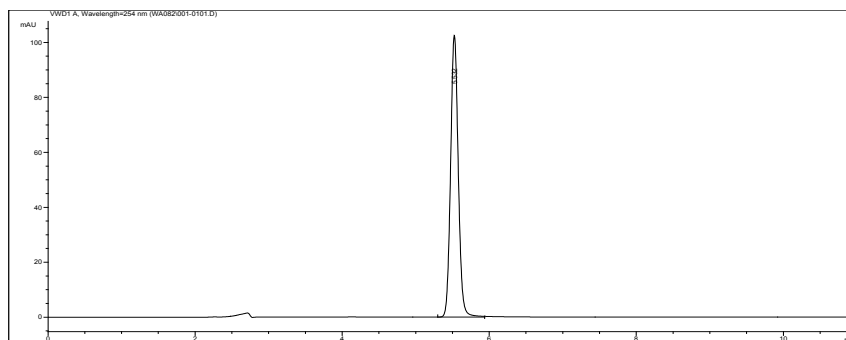
Reference solution: Repeat the procedure using aciclovir CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

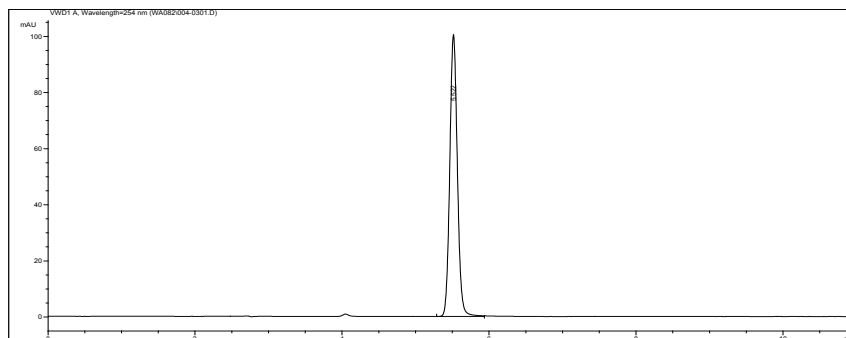
- Column : Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of Aciclovir---HPLC2\WA082\001-0101



The chromatogram of the test solution--- HPLC2\WA082\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.52	718.0	13543	/	1.06

# Aciclovir Chewable Tablets – 阿昔洛韦咀嚼片

Aciclovir (140630-200001) – Method number WA082

## Assays

**Test solution:** Grind 10 tablets to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 mg of acyclovir, in a 250 mL volumetric flask, add 5 mL of 0.4 % sodium hydroxide solution and treat ultrasonically for 1 minute, add a quantity of water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Use the filtrate as the test solution.

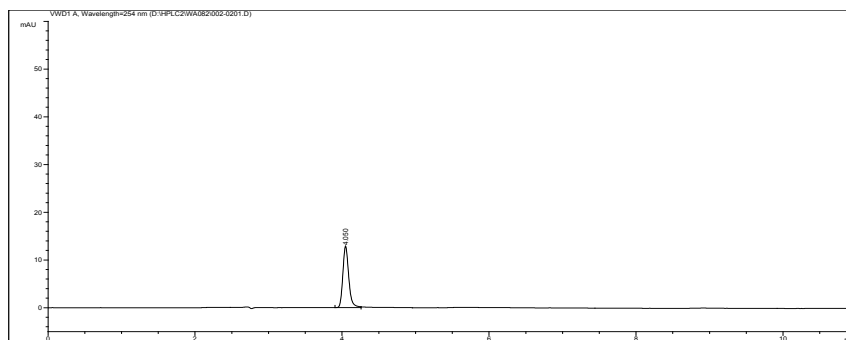
**Reference solution:** Dissolve 10 mg of guanine CRS in a quantity of 0.4 % sodium hydroxide solution in a 100 mL volumetric flask, dilute with water to volume and mix well. Measure accurately 2 mL in a 100 mL volumetric flask, dilute with water to volume, mix well and use as the reference solution.

## Chromatographic conditions

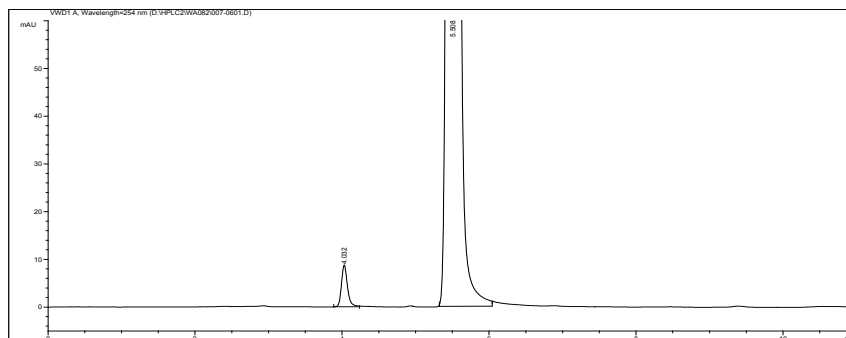
- Column : Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.0



The chromatogram of the reference solution of guanine---HPLC2WA082002-0201



The chromatogram of the test solution--- HPLC2WA082007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Aciclovir	5.52	718.0	13543	/	1.06

# Aciclovir Granules – 阿昔洛韦颗粒

Aciclovir (630-200001) – Method number WA086

## Assay

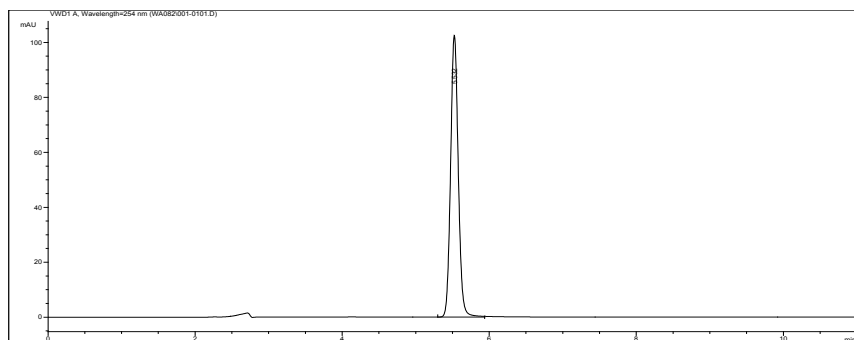
Test solution: Accurately weigh a quantity of the powdered, well-mixed contents, equivalent to about 50 mg of aciclovir in a 250 mL volumetric flask, add 5 mL of 0.4 % sodium hydroxide solution and treat ultrasonically for 1 minute, add a quantity of water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Dilute an accurately measured quantity of the filtrate with water to produce a solution of 20 µg/mL and use as the test solution. Reference solution: Repeat the procedure, using aciclovir CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

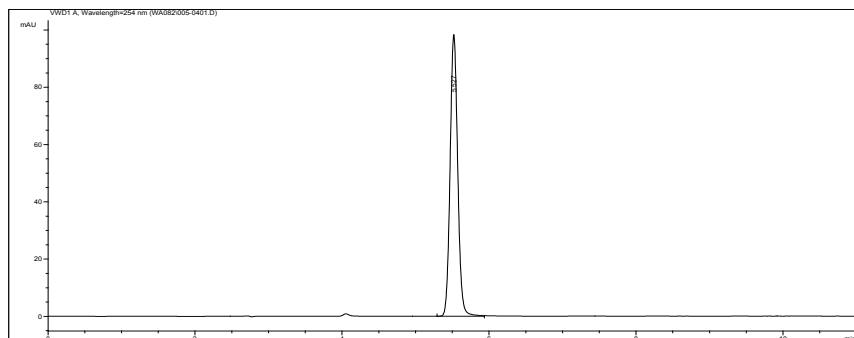
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA08Z001-0101



The chromatogram of the test solution--- HPLC2WA08Z006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.52	723.1	13963	/	1.06

# Aciclovir Granules – 阿昔洛韦颗粒

Aciclovir (630-200001) – Method number WA086

## Assay

Test solution: Accurately weigh a quantity of the powdered, well-mixed contents, equivalent to about 50 mg of aciclovir into a 250 mL volumetric flask, add 5 mL of 0.4 % sodium hydroxide solution and treat ultrasonically for 1 minute, add a quantity of water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Use the filtrate as the test solution.

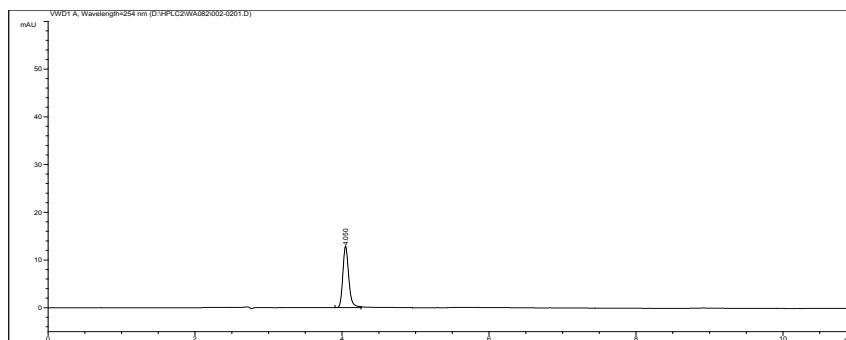
Reference solution: Dissolve 10 mg of guanine CRS in a quantity of 0.4 % sodium hydroxide solution in a 100 mL volumetric flask, dilute with water to volume and mix well. Measure accurately 2 mL in a 100 mL volumetric flask, dilute with water to volume, mix well and use as the reference solution.

## Chromatographic conditions

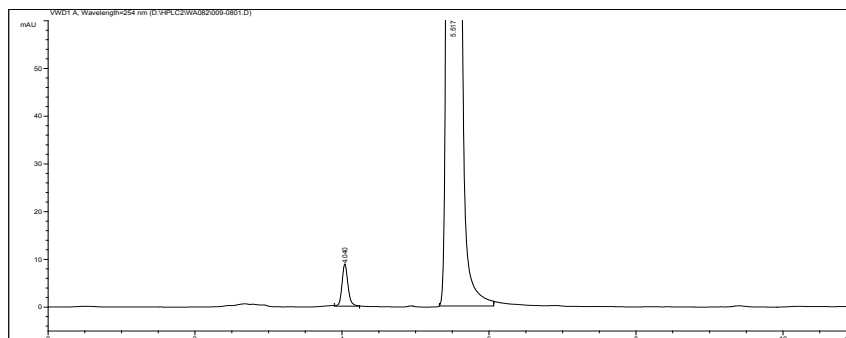
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of guanine---HPLC2WA082002-0201



The chromatogram of the test solution--- HPLC2WA082009-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Guanine	4.04	49.7	12903	/	1.15
Aciclovir	5.52	7249.5	14354	9.0	1.07

# Aciclovir Tablets – 阿昔洛韦片

Aciclovir (140630-200001) – Method number WA081

## Assay

Test solution: Accurately weigh a quantity of the powdered, well-mixed contents, equivalent to about 50 mg of aciclovir in a 250 mL volumetric flask, add 5 mL of 0.4 % sodium hydroxide solution and treat ultrasonically for 1 minute, add a quantity of water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Dilute an accurately measured quantity of the filtrate with water to produce a solution of 20 µg/mL and use as the test solution.

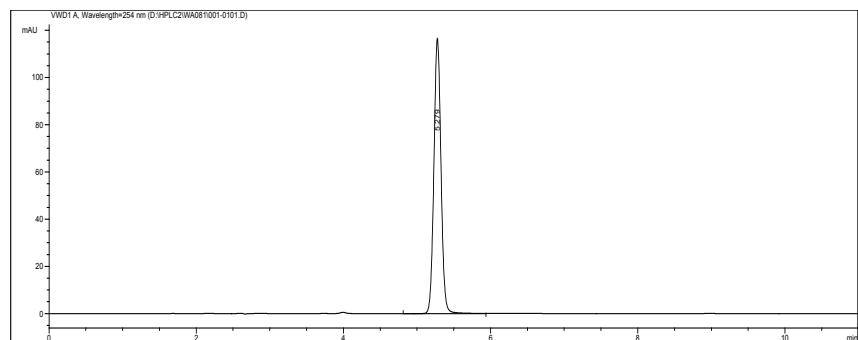
Reference solution: Repeat the procedure, using aciclovir CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

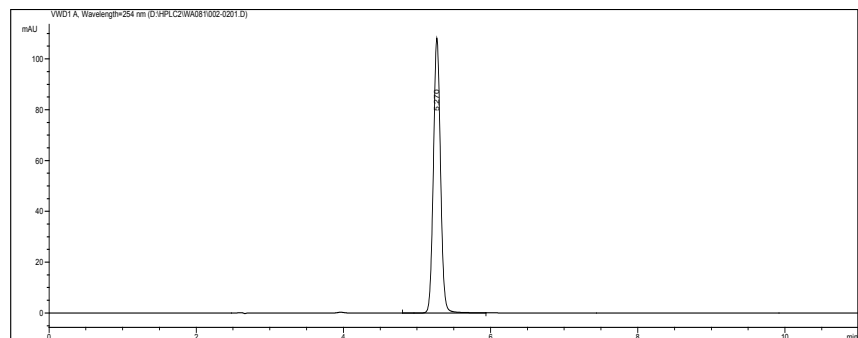
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA081\001-0101



The chromatogram of the test solution --- HPLC2\ WA081\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.27	722.4	13922	/	1.05

# Aciclovir Tablets – 阿昔洛韦片

Aciclovir (140630-200001) – Method number WA081

## Assay

Test solution: Accurately weigh a quantity of the powdered, well-mixed contents, equivalent to about 50 mg of aciclovir into a 250 mL volumetric flask, add 5 mL of 0.4 % sodium hydroxide solution and treat ultrasonically for 1 minute, add a quantity of water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Use the filtrate as the test solution.

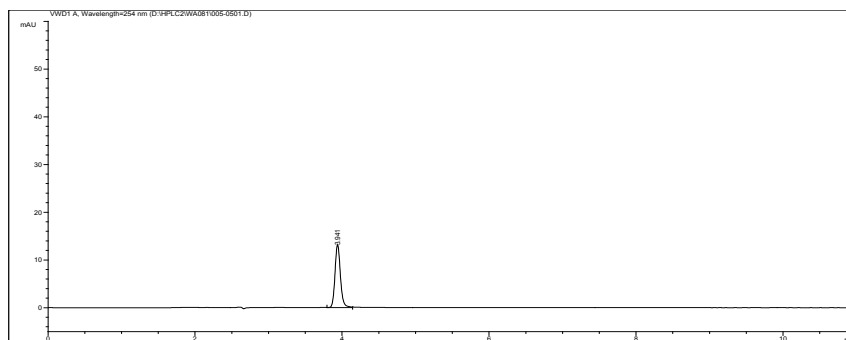
Reference solution: Dissolve 10 mg of guanine CRS in a quantity of 0.4 % sodium hydroxide solution in a 100 mL volumetric flask, dilute with water to volume and mix well. Measure accurately 2 mL in a 100 mL volumetric flask, dilute with water to volume, mix well and use as the reference solution.

## Chromatographic conditions

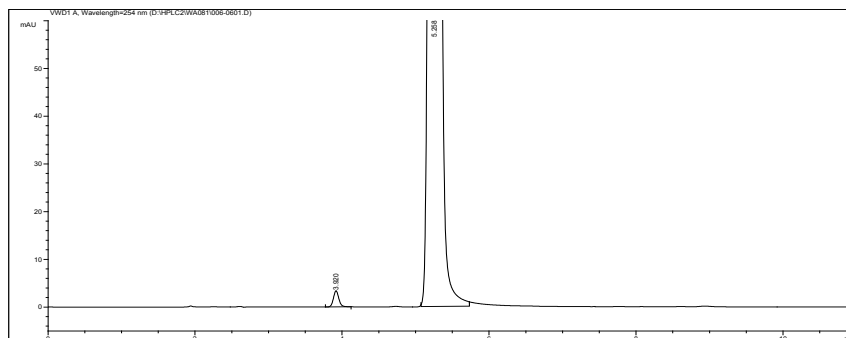
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of guanine---HPLC2WA081\005-0501



The chromatogram of the test solution--- HPLC2\ WA081\006-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Guanine	3.92	17.0	13436	/	1.11
Aciclovir	5.26	6935.6	14745	8.7	1.04



# Aciclovir Ointment – 阿昔洛韦软膏

## Aciclovir (140630-200001) – Method number WA083

### Assay

Test solution: Accurately weigh a quantity of the cream, equivalent to about 50 mg of aciclovir, in a beaker, add 5 mL of 0.4 % sodium hydroxide solution, shake thoroughly for 1 minute in a hot water bath, add 5 g of sodium chloride while stirring, transfer to a 250 mL volumetric flask with a quantity of hot water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Dilute a quantity of the filtrate, accurately measured, with water to produce a solution containing about 20 µg/ml and use as the test solution.

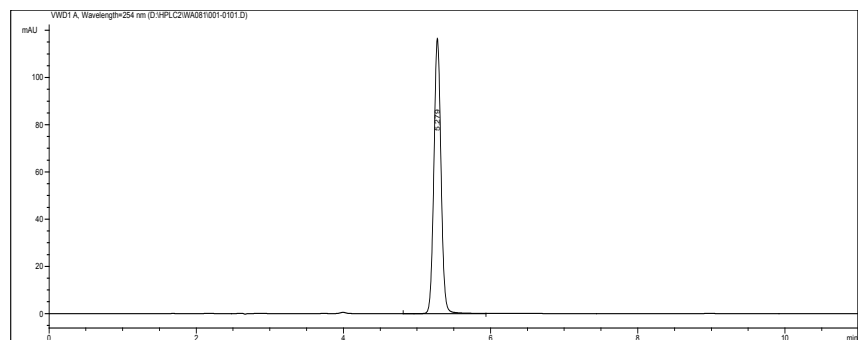
Reference solution: Repeat the procedure, using aciclovir CRS dried to constant weight at 105 °C to produce the reference solution.

### Chromatographic conditions

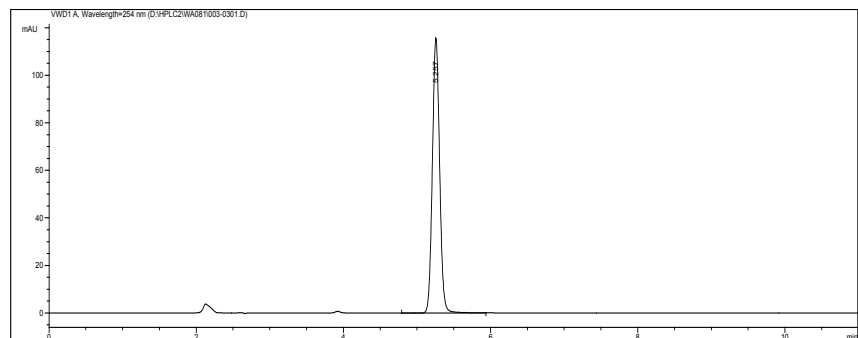
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA081\001-0101



The chromatogram of the test solution--- HPLC2\ WA081\003-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.26	789.2	11282	/	1.041

# Aciclovir Ointment – 阿昔洛韦软膏

## Aciclovir (140630-200001) – Method number WA083

### Assay

Test solution: Accurately weigh a quantity of the cream, equivalent to about 50 mg of aciclovir, in a beaker, add 5 mL of 0.4 % sodium hydroxide solution, shake thoroughly for 1 minute in a hot water bath, add 5 g of sodium chloride while stirring, transfer to a 250 mL volumetric flask with a quantity of hot water and shake for 10 minutes in a hot water bath, allow to cool to room temperature, dilute with water to volume, mix well and filter. Use the filtrate as the test solution.

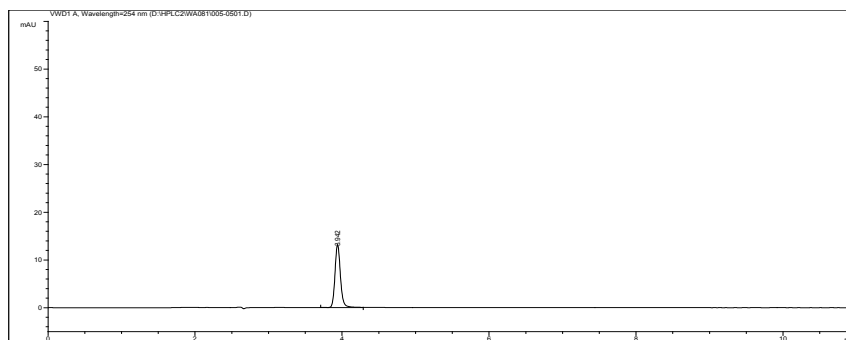
Reference solution: Dissolve 10 mg of guanine CRS in a quantity of 0.4 % sodium hydroxide solution in a 100 mL volumetric flask, dilute with water to volume and mix well. Measure accurately 2 mL in a 100 mL volumetric flask, dilute with water to volume, mix well and use as the reference solution.

### Chromatographic conditions

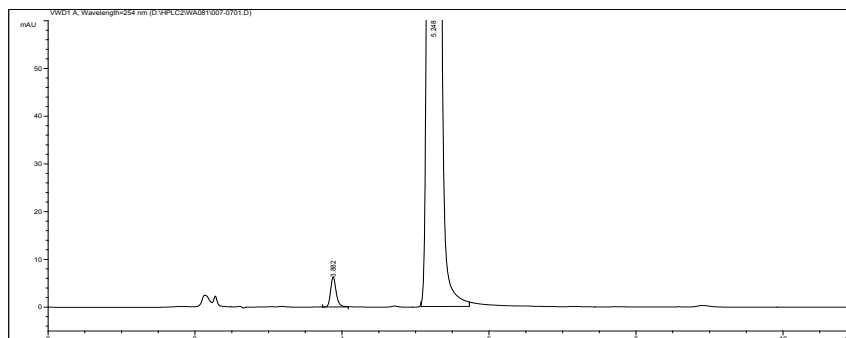
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of guanine---HPLC2\WA081\005-0501



The chromatogram of the test solution--- HPLC2\WA081\007-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Guanine	3.88	33.3	13022	/	1.20
Aciclovir	5.25	7135.5	14691	8.8	1.05

# Estazolam – 艾司唑仑

Estazolam (1219-0102) – Method number WR024

## Assay

Test solution: Dissolve a quantity in mobile phase to produce a solution of 0.2 mg/mL and use as the test solution.

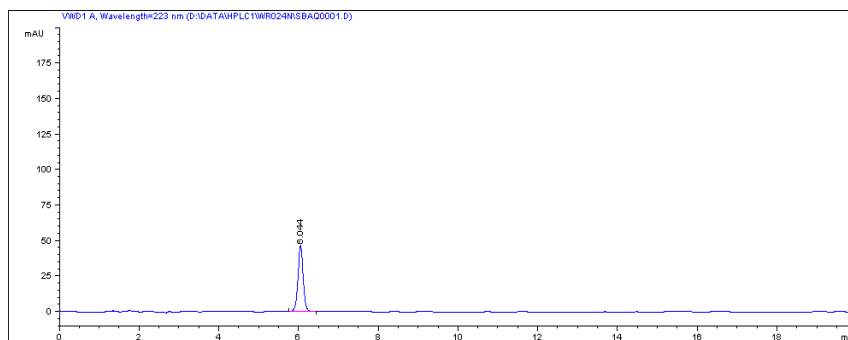
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce a solution of 2 µg/mL and use as the reference solution.

## Chromatographic conditions

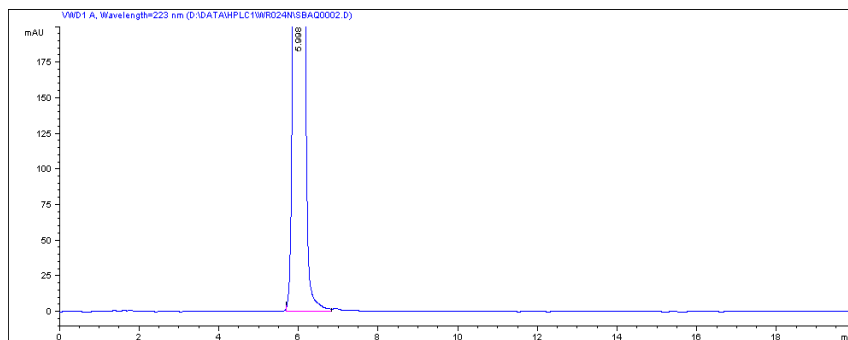
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water:methanol=35:65
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 223 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WR024\NSBAQ0001



The chromatogram of the test solution--- HPLC1\WR024\NSBAQ0002

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Estazolam	6.00	36033.0	9097	/	1.06

# Estazolam Tablets – 艾司唑仑片

Estazolam (1219-0102) – Method number WR025

## Assay

Test solution: Dissolve a quantity of the powder, equivalent to about 2 mg of estazolam, in mobile phase to produce a solution containing 0.2 mg/mL, filter and use the filtrate as the test solution.

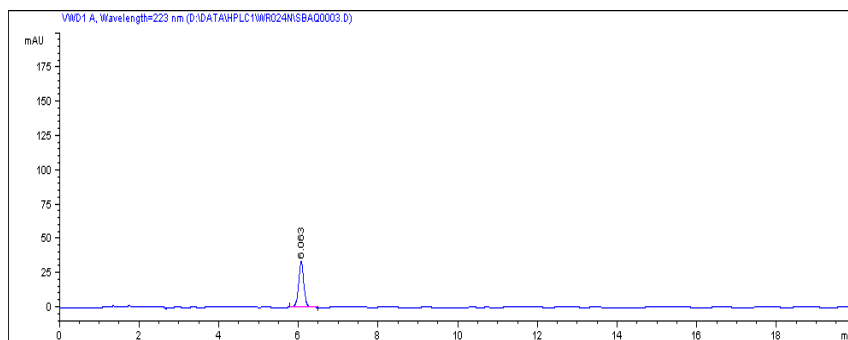
Reference solution: Dilute a quantity of the test solution, accurately measured, with mobile phase to produce a solution of 2 µg/mL as the reference solution.

## Chromatographic conditions

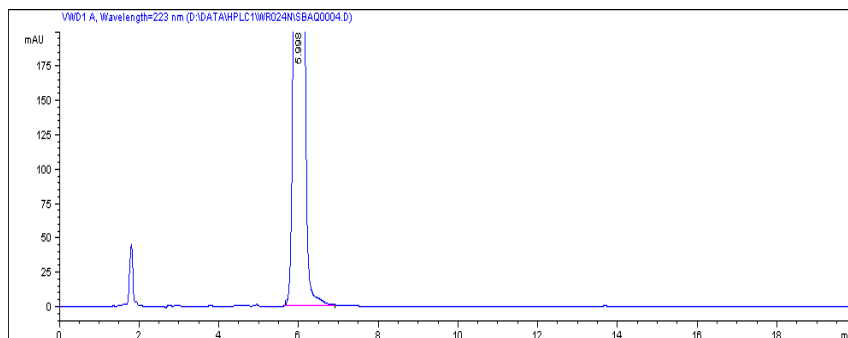
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water:methanol=35:65
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 223 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WR024\NSBAQ0003



The chromatogram of the test solution--- HPLC1\WR024\NSBAQ0004

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Estazolam	6.00	30961.6	9723	/	1.06

# Metamizole Sodium Nasal drops – 安乃近滴鼻液

Metamizole (0002-9504) – Method number WA042

## Assay

Test solution: Dilute 2 mL of the nasal drops, accurately measured in a 100 mL volumetric flask, with a mixture of methanol-water (70:30) to volume, mix well and use as the test solution.

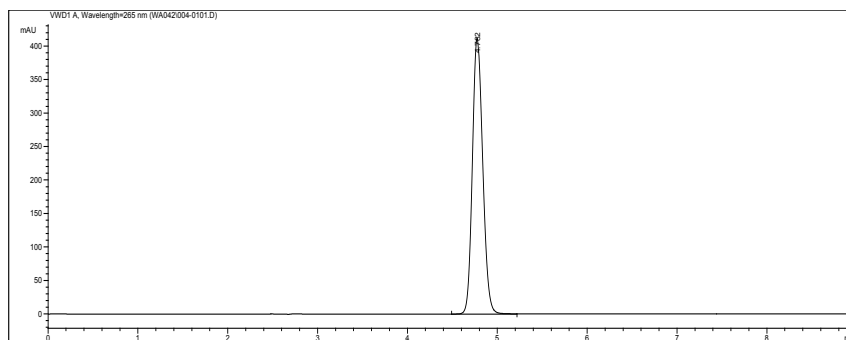
Reference solution: Dilute a quantity of metamizole sodium CRS with methanol-water (70:30) to produce the solution of 0.4 mg/ml and use as the reference solution.

## Chromatographic conditions

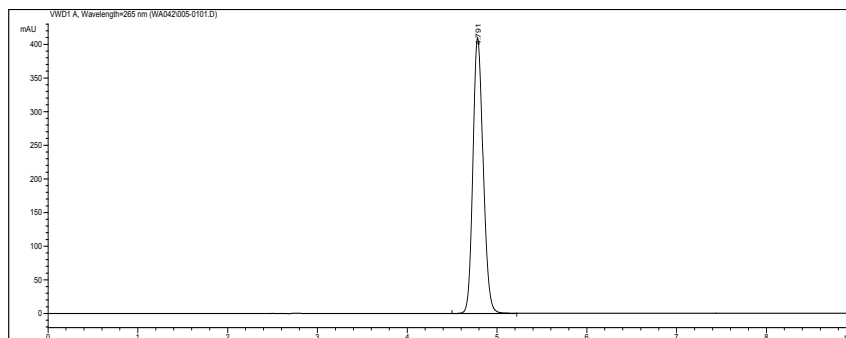
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol : phosphate BS (dissolve 6.8 g of potassium dihydrogen phosphate with 1000 mL of water, adjust pH to 4.5±0.5 with phosphoric acid ) = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 265 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA042\004-0101



The chromatogram of the test solution --- HPLC1\WA042\005-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Metamizole	4.79	3231.7	8411	/	1.09

# Ampicillin – 氨苄西林

Ampicillin (0410-200004) – Method number WR189

## Assay

Test solution: Dissolve about 30 mg, accurately weighed, in mobile phase A to produce a solution of 3 mg/mL and use as the test solution.

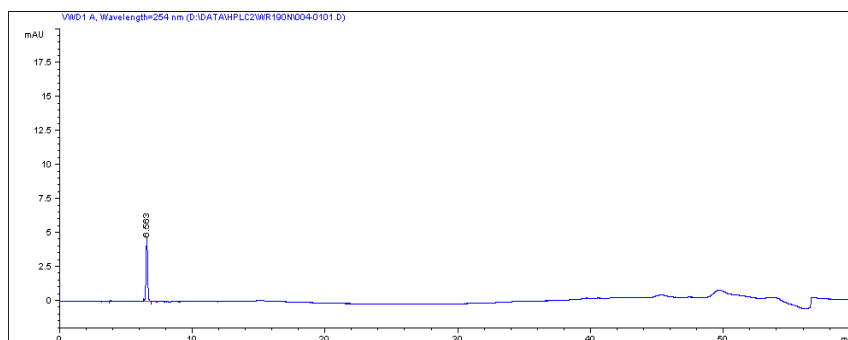
Reference solution: Transfer accurately 1 mL of the test solution to a 100 mL volumetric flask, dilute with mobile phase A to volume, mix well and use as the reference solution.

## Chromatographic conditions

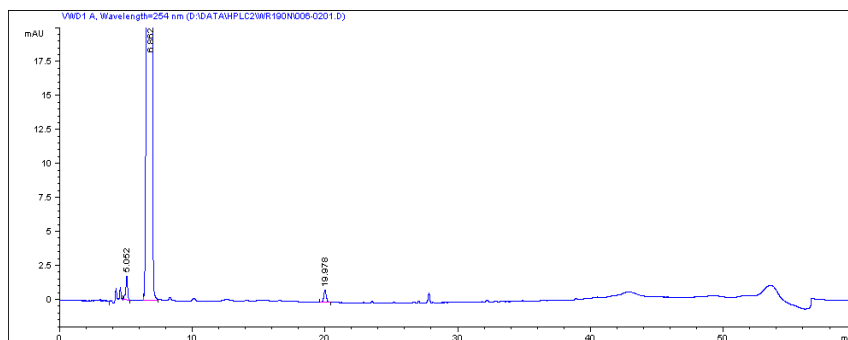
- Column: Agilent ZORBAX SB-Aq 4.6x250 mm, 5 µm (880975-914)
- Mobile phase: A: 12 % acetic acid solution-0.2 mol/L potassium dihydrogen phosphate solution-acetonitrile-water (0.5:50:50:900) B: 12 % acetic acid solution-0.2 mol/L potassium dihydrogen phosphate solution-acetonitrile-water (0.5:50:400:550) gradient elute: 0 min: 85 %A; 10 min: 85 %A; 40 min: 0 %A; 50 min: 0 %A; 51 min: 85 %A; 60 min: 85 %A
- Flow rate: 1 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR190N004-0101.D



The chromatogram of the test solution--- HPLC2WR190N006-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	5.05	17.8	7478	/	0.80
Ampicillin	6.86	4035.2	2747	4.8	0.70
Impurity2	19.98	11.8	58671	30.7	0.97

# Ampicillin Sodium – 氨苄西林钠

## Ampicillin (0410-200004) – Method number WR190

### Assay

Test solution: Dissolve about 30 mg, accurately weighed, in mobile phase A to produce a solution of 3 mg/mL and use as the test solution.

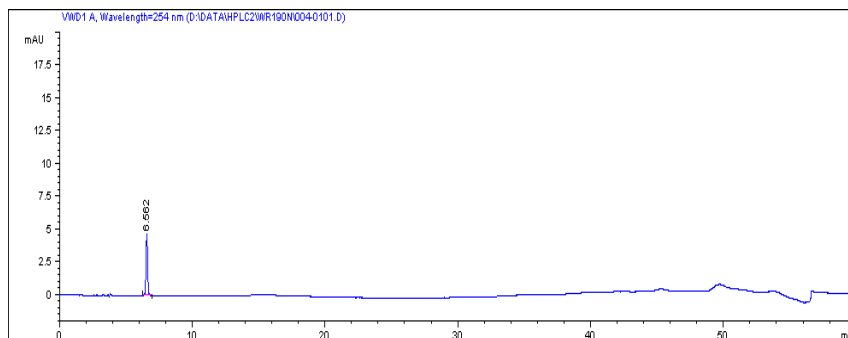
Reference solution: Transfer accurately 1 mL of the test solution to a 100 mL volumetric flask, dilute with mobile phase A to volume, mix well and use as the reference solution.

### Chromatographic conditions

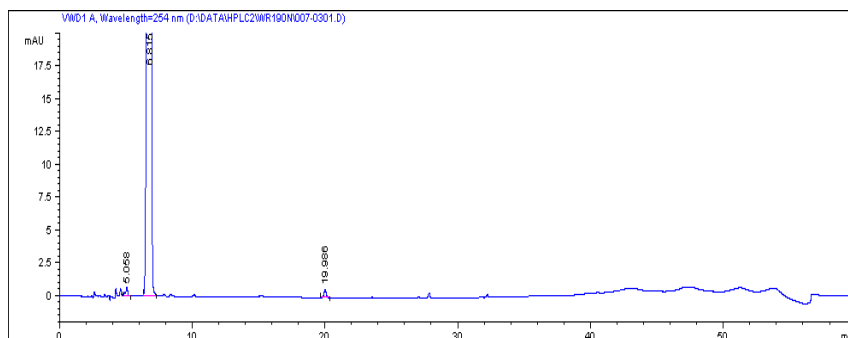
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 μm (880975-914)
- Mobile phase: A: 12 % acetic acid solution-0.2mol/L potassium dihydrogen phosphate solution-acetonitrile-water (0.5:50:50:900) B: 12 % acetic acid solution-0.2mol/L potassium dihydrogen phosphate solution-acetonitrile-water (0.5:50:400:550) gradient elute: 0 min: 85 %A; 10 min: 85 %A; 40 min: 0 %A; 50 min: 0 %A; 51 min: 85 %A; 60 min: 85 %A
- Flow rate: 1 mL/min
- Injection volume: 20 μL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR190N004-0101.D



The chromatogram of the test solution--- HPLC2WR190N007-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	5.06	7.2	7323	/	/
Ampicillin	6.82	3049.7	3677	5.1	0.73
Impurity2	19.99	7.8	68624	34.9	0.97

# Amrinone – 氨力农

Amrinone (ACROS) – Method number WA152

## Assay

Test solution: Accurately weigh 25 mg in a 50 ml volumetric flask, add 2 mL of a 0.1 mol/L hydrochloride acid solution, treat ultrasonically until dissolved. Dilute to volume with mobile phase, mix well and use as the test solution.

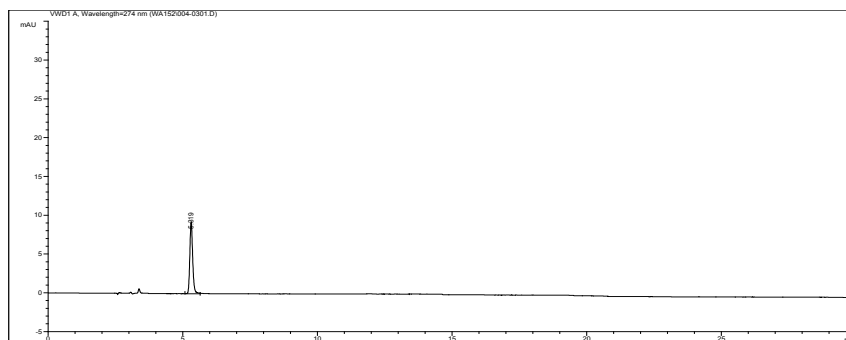
Reference solution: Accurately measured 1 ml of the test solution in a 100 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the reference solution.

## Chromatographic conditions

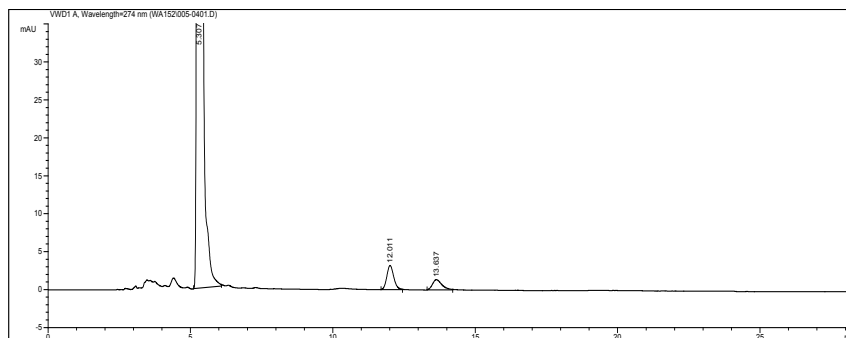
- Column : Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 μm (880668-901)
- Mobile phase: methanol-acetonitrile-0.01Mpotassium dihydrogen phosphate solution(adjust pH to 6.2±0.05 with 1 mol/L potassium hydroxide solution)=15:10:75
- Flow rate: 1.0 mL/min Injection volume: 20 μL
- Column temperature: 30 °C
- Detector wavelength: 274 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA152\004-0301



The chromatogram of the test solution--- HPLC1\ WA152\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Amrinone	5.31	6999.2	14329	/	1.21
Impurity1	12.01	53.8	12310	21.9	1.16
Impurity2	13.64	30.7	8800	3.2	1.46



# Omeprazole Enteric-coated Capsules – 奥美拉唑肠溶胶囊

Omeprazole – Method number WA201

## Assay

Test solution: Accurately weigh the contents of 20 capsules and grind to a fine powder. Accurately weigh a quantity, equivalent to about 20 mg of omeprazole, in a 100 mL volumetric flask, add 20 mL of ethanol and about 60 mL of phosphate BS (pH 11.0), treat ultrasonically to dissolve the omeprazole, dilute with phosphate BS (pH 11.0) to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

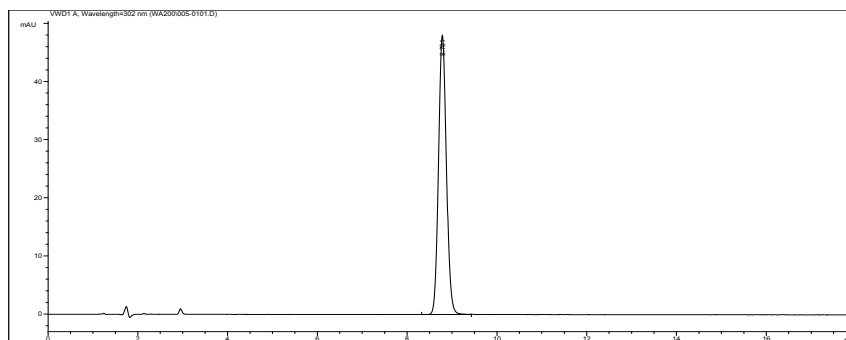
Reference solution: Repeat the procedure using omeprazole CRS to produce the reference solution.

## Chromatographic conditions

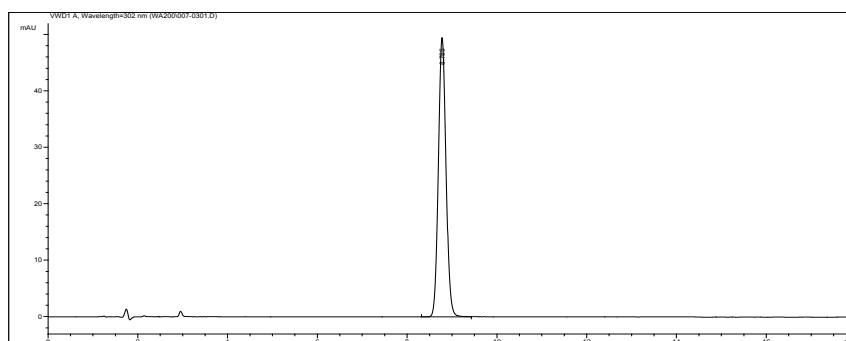
- Column: Agilent ZORBAX XDB-C8 4.6×150 mm, 5 µm (993967-906)
- Mobile phase: 0.01 mol/L disodium hydrogen phosphate solution (adjust pH to 7.6 with phosphoric acid):acetonitrile=77: 23
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 302 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA200\005-0101



The chromatogram of the test solution--- HPLC1\WA200\007-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Omeprazole	8.78	581E±E3	11932	/	1.05

# Omeprazole Enteric-coated Tablets – 奥美拉唑肠溶片

Omeprazole – Method number WA200

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity, equivalent to about 20mg of omeprazole, in a 100 mL volumetric flask, add 20 mL of ethanol and about 60 mL of phosphate BS (pH 11.0), treat ultrasonically to dissolve the omeprazole, dilute with phosphate BS (pH 11.0) to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

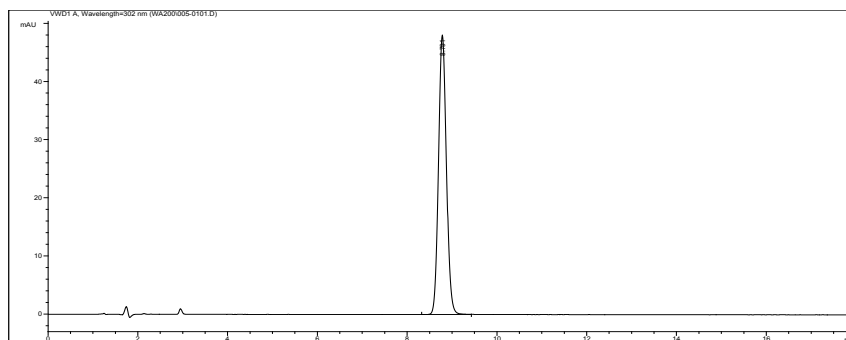
Reference solution: Repeat the procedure using omeprazole CRS to produce the reference solution.

## Chromatographic conditions

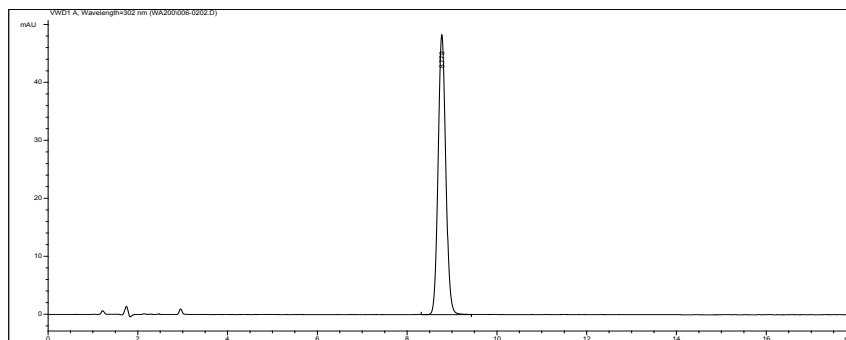
- Column: Agilent ZORBAX XDB-C8 4.6×150 mm, 5 µm (993967-906)
- Mobile phase: 0.01 mol/L disodium hydrogen phosphate solution (adjust pH to 7.6 with phosphoric acid) : acetonitrile=77: 23
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 302 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA200\005-0101



The chromatogram of the test solution --- HPLC1\WA200\006-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Omeprazole	8.78	569.4	11325	/	1.05

# Oxaprozin – 奥沙普秦

Oxaprozin (100353-200301) – Method number WR110

## Assay

Test solution: Protect from light throughout the procedure. Dissolve a quantity in acetonitrile to produce the test solution containing 2.0 mg/mL.

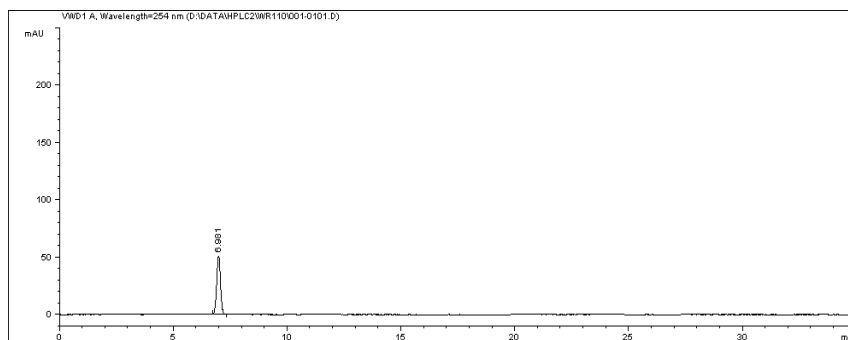
Reference solution: Dilute an accurately measured quantity of the test solution with acetonitrile to produce the reference solution containing 20 µg/mL.

## Chromatographic conditions

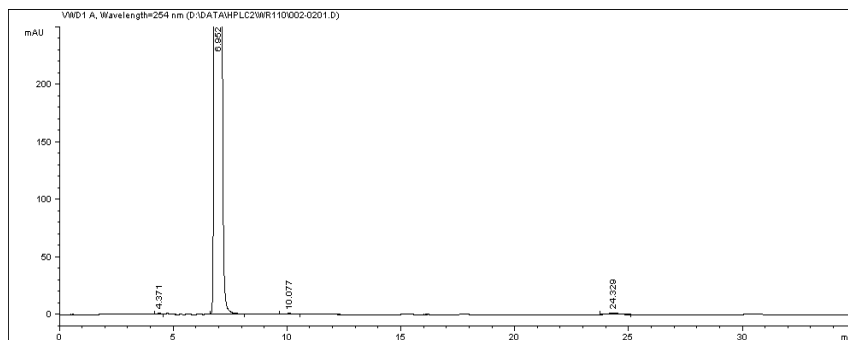
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile-water (adjust pH to 2.5 with phosphoric acid)=55 : 45
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR110001-0101.D



The chromatogram of the test solution--- HPLC2WR110002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Oxaprozin	6.95	40937.1	4547	8.0	1.04
Impurity1	4.37	11.0	5870	/	0.88
Impurity2	10.08	15.2	8665	7.4	1.09
Impurity3	24.33	39.1	17977	24.6	1.01

# Oxaprozin Enteric-coated Capsules – 奥沙普秦肠溶胶囊

Oxaprozin (100353-200301) – Method number WA198

## Assay

Test solution: Dissolve a quantity of the contents of the capsules in acetonitrile to produce a solution of 2 mg/mL, filter and use the filtrate as the test solution.

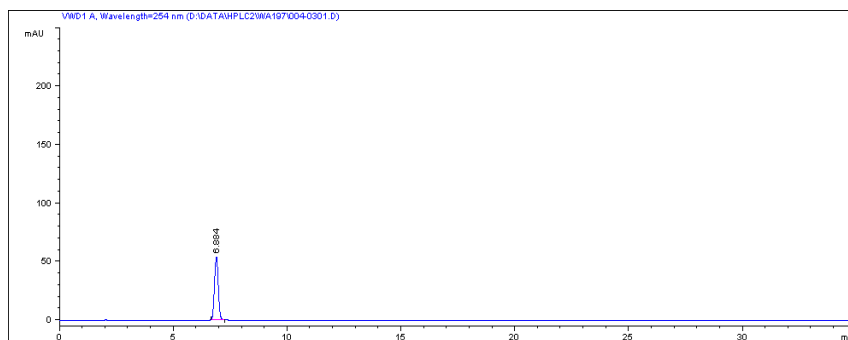
Reference solution: Dilute an accurately measured quantity of the test solution with acetonitrile to produce the reference solution of 20 µg/ml.

## Chromatographic conditions

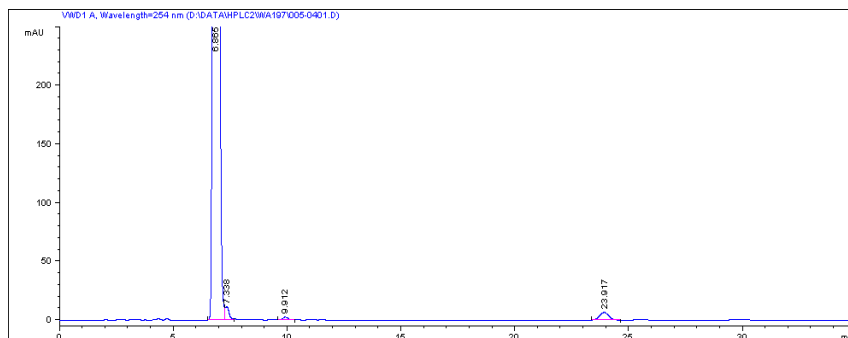
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile: water(adjust pH to 2.5 with phosphoric acid) = 55 : 45
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA197004-0301



The chromatogram of the test solution--- HPLC2WA197005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Oxaprozin	6.87	40811.2	4317	/	1.06
Impurity1	7.34	129.1	9507	1.3	/
Impurity2	9.91	37.3	9430	7.2	1.16
Impurity3	23.92	176.9	17373	24.7	1.02

# Oxaprozin Enteric-coated Tablets – 奥沙普秦肠溶片

Oxaprozin (100353-200301) – Method number WA197

## Assay

Test solution: Remove the coatings from 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in acetonitrile to produce a solution of 2 mg/mL, filter and use the filtrate as the test solution.

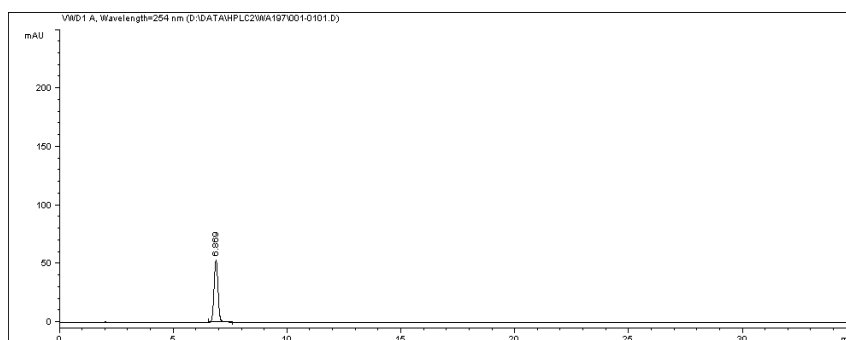
Reference solution: Dilute an accurately measured quantity of the test solution with acetonitrile to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

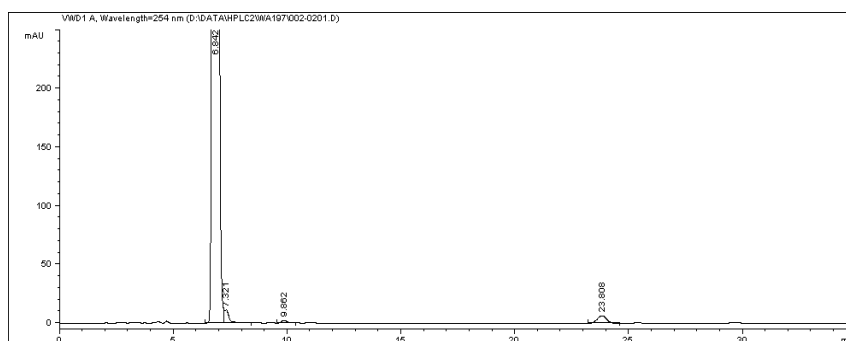
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile:water (adjust pH to 2.5 with phosphoric acid) = 55:45
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA197001-0101



The chromatogram of the test solution--- HPLC2WA197002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Oxaprozin	6.84	40806.7	4232	/	1.05
Impurity1	7.32	129.3	9378	1.3	/
Impurity2	9.86	37.9	8971	7.1	1.19
Impurity3	23.81	176.7	16831	24.2	1.03

# Betamethasone – 倍他米松

Betamethasone (0118-9502) – Method number WR081

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase and dilute with the same solvent to produce a solution of 0.4 mg/mL and use as the test solution.

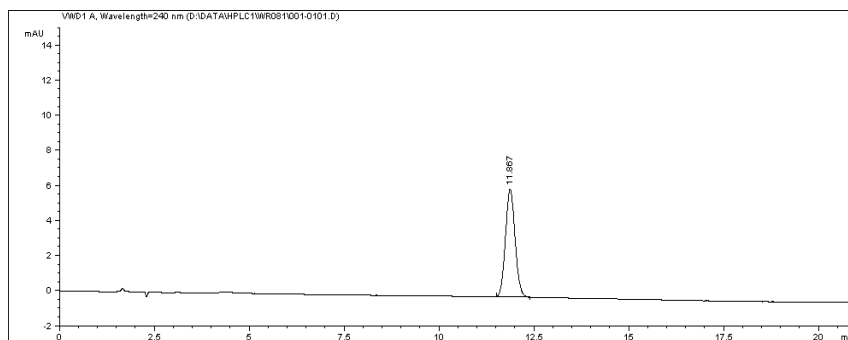
Reference solution: Transfer 1 mL of the test solution, accurately measured, to a 100 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the reference solution.

## Chromatographic conditions

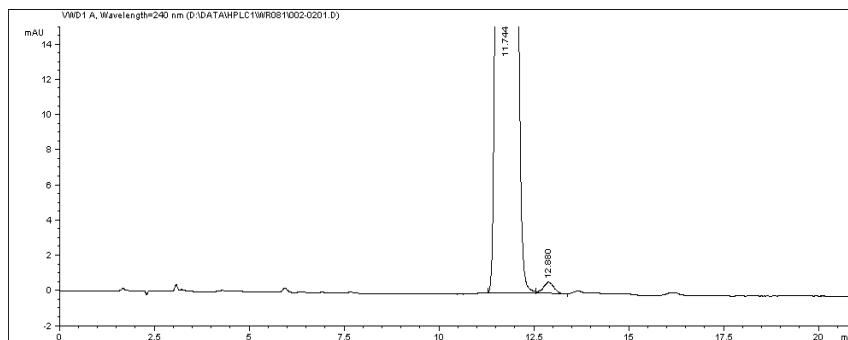
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR081\004-0302



The chromatogram of the test solution ---HPLC1\WR081\002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Betamethasone	11.74	10154.8	10532	/	1.04
Methyl prednisolone	12.88	13.2	10316	2.4	0.99

# Betamethasone Sodium Phosphate – 倍他米松磷酸钠

## Betamethasone Sodium Phosphate (10016-0011) – Method number WA142

### Assay

Test solution: Dissolve a quantity of the substance in mobile phase to produce a solution of 2.5 mg/ml and use as the test solution.

Reference solution: Dilute an accurately measured quantity of the test solution to produce a solution of 50 µg/mL as the reference solution.

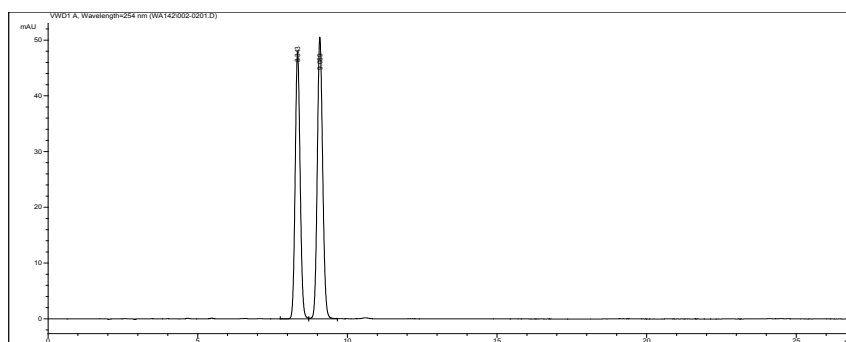
Dissolve a quantity of betamethasone sodium phosphate CRS and dexamethasone sodium phosphate CRS in mobile phase to make a solution of 40 µg/mL each for the system suitability test.

### Chromatographic conditions

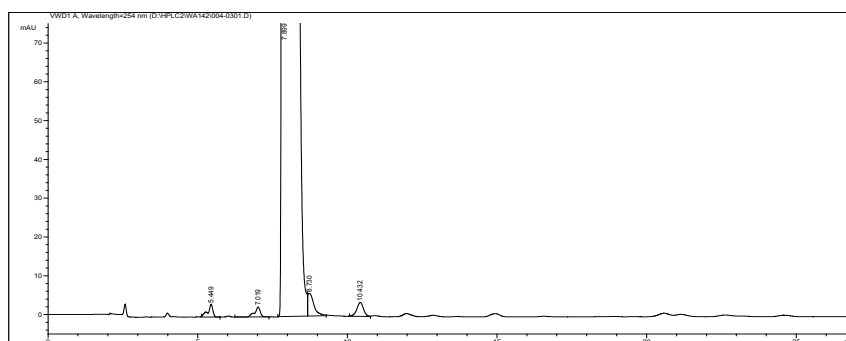
- Column : ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: potassium dihydrophosphate hexylamine solution (mix 1.36g of potassium dihydrophosphate with 0.60g of hexylamine, stand for 10 minutes, then dissolve it in 185 mL water): acetonitrile=78 :22
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the system suitability---HPLC2\WA142\002-0201



The chromatogram of the test solution---HPLC2\WA142\004-0301

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Betamethasone Sodium Phosphate	8.34	551.6	11643	/	1.05
Dexamethasone Sodium Phosphate	9.09	632.9	10508	2.24	1.06

# Betamethasone Sodium Phosphate Injection

Betamethasone Sodium Phosphate (10016-0011) – Method number WR084

倍他米松磷酸钠注射液

## Assay

Internal standard solution: dissolve a quantity of ethyl p-hydroxybenzoate in methanol to produce a solution of 0.1mg per ml, mix well.

Test solution: Transfer 2 mL of the injection fluid, accurately measured, to a 50 mL volumetric flask, dilute with water to volume, mix well, accurately measure 5 mL in a 25 mL volumetric flask, accurately add 5 mL of internal standard solution, dilute with water to volume, mix well and use as the test solution.

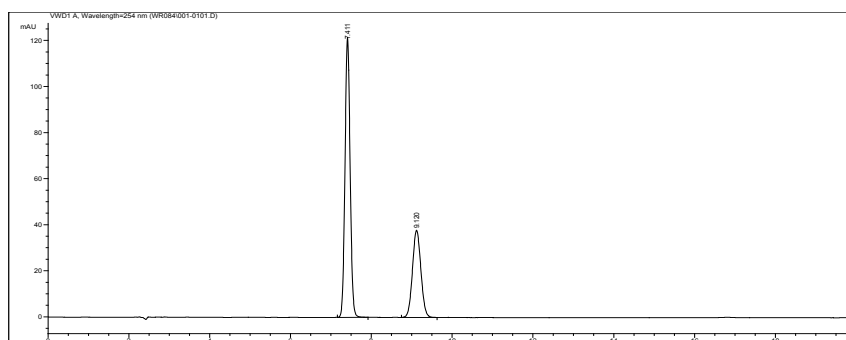
Reference solution: Dissolve a quantity of betamethasone sodium phosphate CRS, accurately weighed, in water to produce a solution of about 0.21 mg/mL, calculated on the anhydrous basis. Accurately measure 5 mL each of the solution and the internal standard solution in a 25 mL volumetric flask, dilute with water to volume, mix well and use as the reference solution.

## Chromatographic conditions

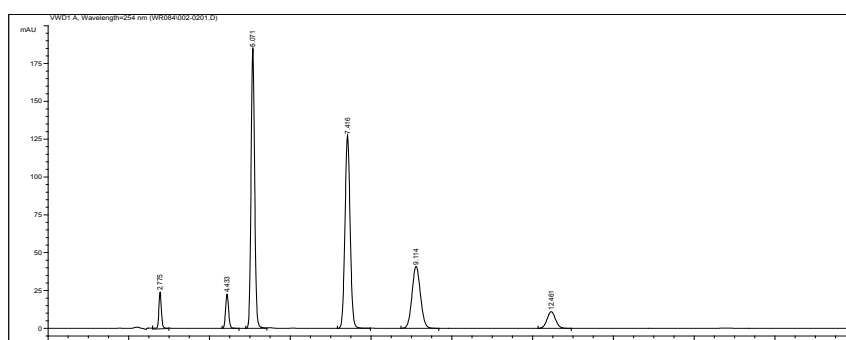
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol -0.05M potassium dihydrogen phosphate solution ( 55:45)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WR084004-0302



The chromatogram of the test solution ---HPLC2WR084002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ethyl 4-hydroxybenzoate	7.42	1141.5	15038	/	1.04
Betamethasone Sodium Phosphate	9.12	602.7	8852	5.4	1.05



# Betamethasone Tablets – 倍他米松片

Betamethasone (0118-9502) – Method number WR082

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Transfer an accurately weighed quantity of the powder, equivalent to about 2 mg of betamethasone, to a 50 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically for 30 minutes until the betamethasone dissolves. Allow to cool and dilute with mobile phase to volume, mix well, filter through a membrane and use the filtrate as the test solution.

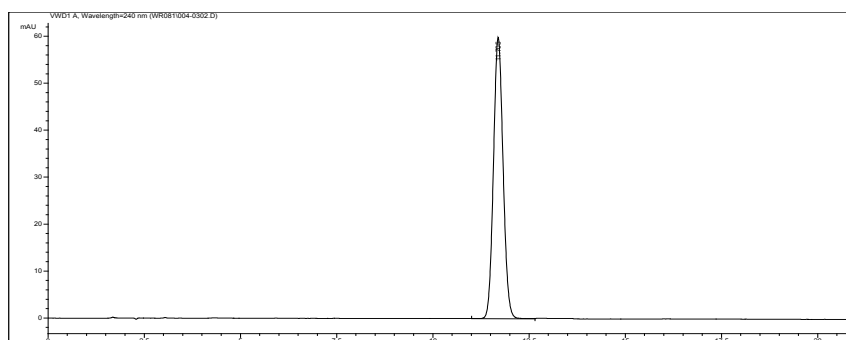
Reference solution: Dilute a quantity of betamethasone CRS with mobile phase to produce a solution of 40 µg/mL, mix well and use as the reference solution.

## Chromatographic conditions

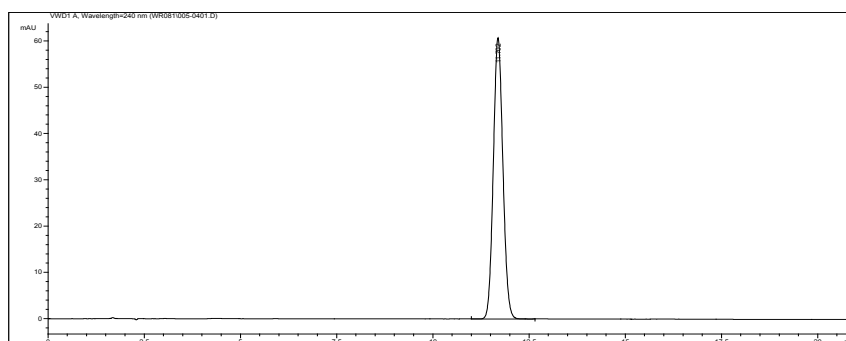
- Column: Agilent ZORBAX SB C18 4.6×250 mm, µm (880975-902)
- Mobile phase: methanol:water=60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.0



The chromatogram of the reference solution---HPLC2WR081004-0302



The chromatogram of the test solution---HPLC2WR081005-0401

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Betamethasone	11.70	1052.1	9411	/	1.05

# Betamethasone Ointment – 倍他米松软膏

Betamethasone (0118-9502) – Method number WR083

## Assay

Test solution: Dissolve a quantity of the substance, equivalent to about 1 mg of betamethasone, accurately weighed, in 50 ml of methanol and mix for 30 seconds at 9500 rpm with a homogenizer, filter through a millipore membrane (0.45 µm), discard the initial 5 mL of the filtrate, use the successive filtrate as the test solution.

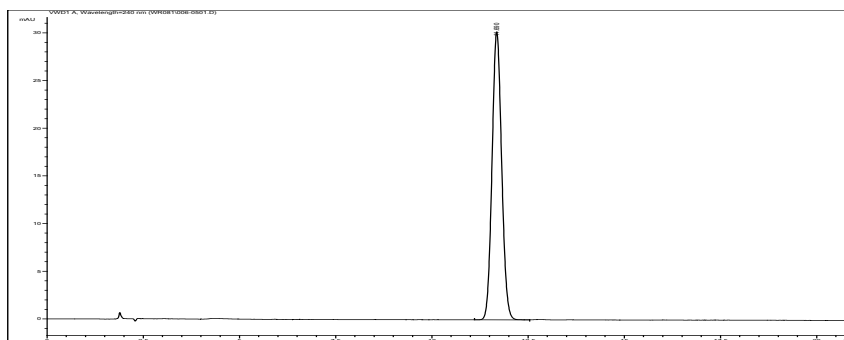
Reference solution: Dissolve a quantity of betamethasone CRS, accurately weighed, in the mobile phase to produce a solution of 20 µg/ml and use as the reference solution.

## Chromatographic conditions

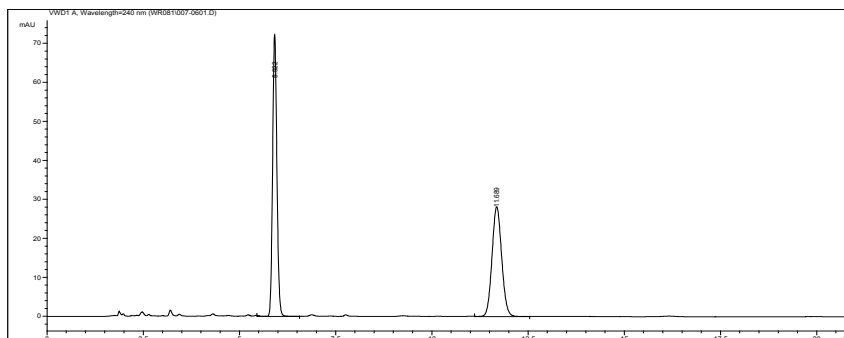
- Column: Agilent ZORBAX SB C18 4.6X250 mm, 5 µm (880975-902)
- Mobile phase: methanol-water=58:42
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution--HPLC2\WR081\006-0501



The chromatogram of the test solution---HPLC2\WR081\007-0601

Constituents	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Betamethasone	11.69	492.5	10434		1.034

# Oxacillin Sodium – 苯唑西林钠

Oxacillin Sodium (0482-9901) – Method number WR070

## Assay

Test solution: Dissolve an accurately weighed quantity in water to produce the test solution of 1 mg/mL.

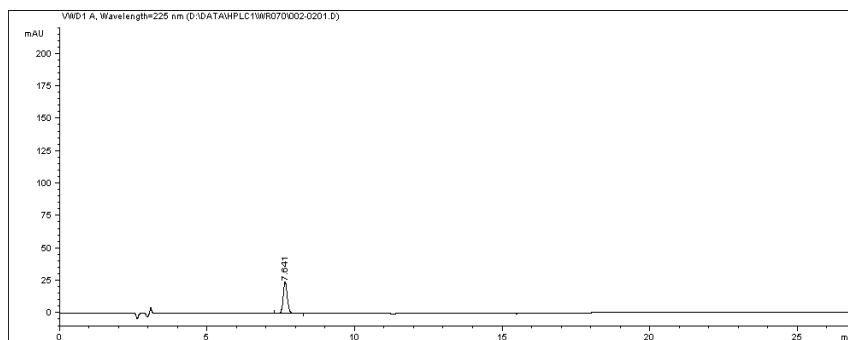
Reference solution: Dilute an accurately measured quantity of the test solution with water to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

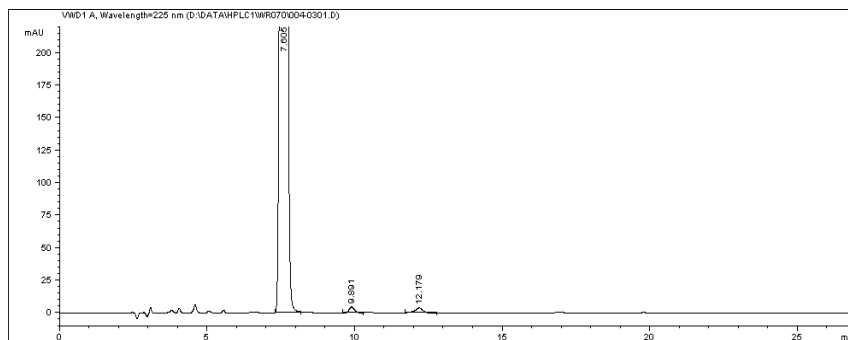
- Column: Agilent ZORBAX SB-Phenyl 4.6X250 mm, 5 µm (880975-912)
- Mobile phase: 0.02 mol/L potassium dihydrogen phosphate (adjust pH to 3.6 with phosphoric acid)- acetonitrile-methanol (60: 27.5:12.5)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR070\002-0201



The chromatogram of the test solution --- HPLC2\WR070\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Oxacillin	7.61	21719.8	9177	/	0.91
Impurity1	9.89	58.1	15127	7.1	1.11
Impurity2	12.18	73.8	12419	6.0	0.83

# Piracetam – 吡拉西坦

Piracetam (100386-200301) – Method number WA064

## Assay

Test solution: Prepare a solution of 0.5 mg piracetam per mL mobile phase.

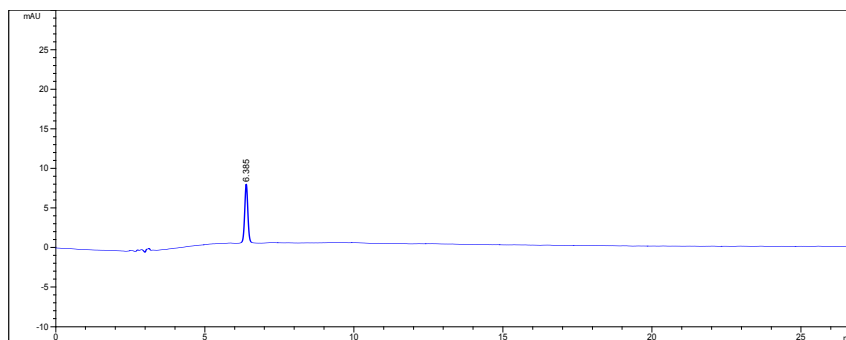
Reference solution: Prepare a solution of 5 µg of piracetam CRS per mL mobile phase.

## Chromatographic conditions

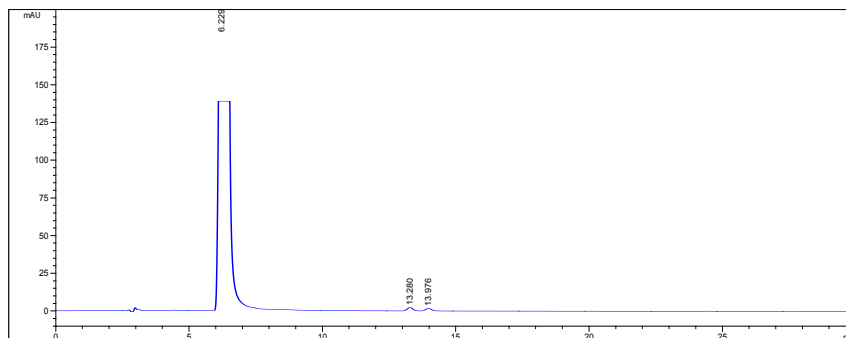
- Column: Agilent TC-C18 4.6×250 mm, 5 µm (518925-902)
- Mobile phase: methanol: water =7:93
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 25 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2



The chromatogram of the test solution--- HPLC2

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Piracetam	6.229	46220.9	3973	/	1.641
Impurity 1	13.28	34.2	18182	16.9	1.036
Impurity 2	13.976	26.7	18669	1.77	1.009

# Piracetam Capsules – 吡拉西坦胶囊

## Piracetam (100386-200301) – Method number WA072

### Assay

Test solution: Accurately weigh and dissolve a quantity of the well-mixed contents, equivalent to about 0.1 g of piracetam, in mobile phase in a 100 mL volumetric flask, shake to dissolve the piracetam and dilute to volume, mix well and filter, accurately transfer 5 mL of the filtrate to a 50 mL volumetric flask and dilute with mobile phase to volume, mix well. Use the resulting solution as the test solution.

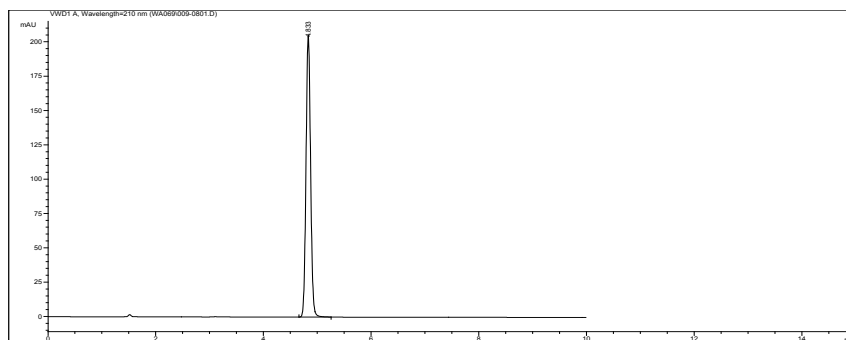
Reference solution: Repeat the procedure using piracetam CRS to produce the reference solution.

### Chromatographic conditions

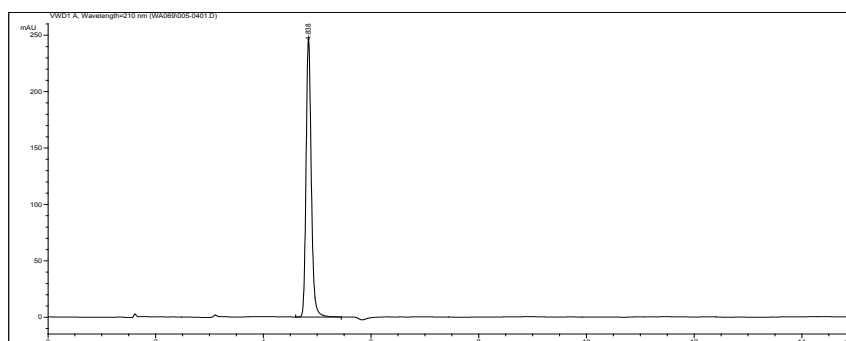
- Column: Agilent Hypersil ODS-C18 4.6×250 mm, 5 µm (7991618-584)
- Mobile phase: methanol : water =10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature : 30 °C
- Detector wavelength: 210 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA069\009-0801



The chromatogram of the test solution--- HPLC2\ WA069\006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Piracetam	4.84	1575.2	11055	/	1.14

# Piracetam Oral Solution – 吡拉西坦口服溶液

Piracetam(100386-200301) – Method number WA069

## Assay

Test solution: Dilute a quantity of the solution, accurately measured, with mobile phase to produce a solution of 0.1 mg of piracetam per mL as the test solution.

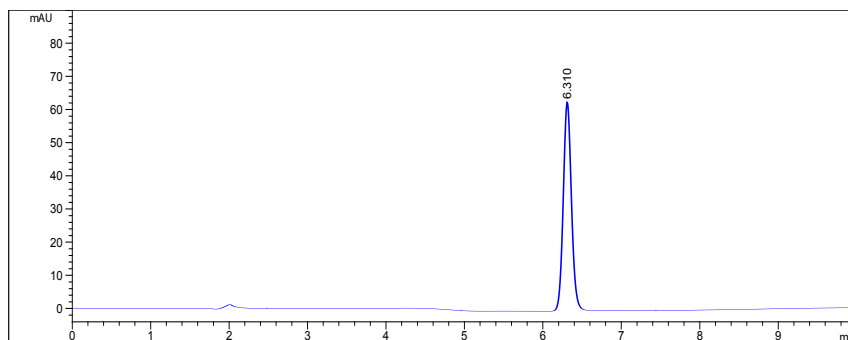
Reference solution: Repeat the procedure using piracetam CRS to produce the reference solution.

## Chromatographic conditions

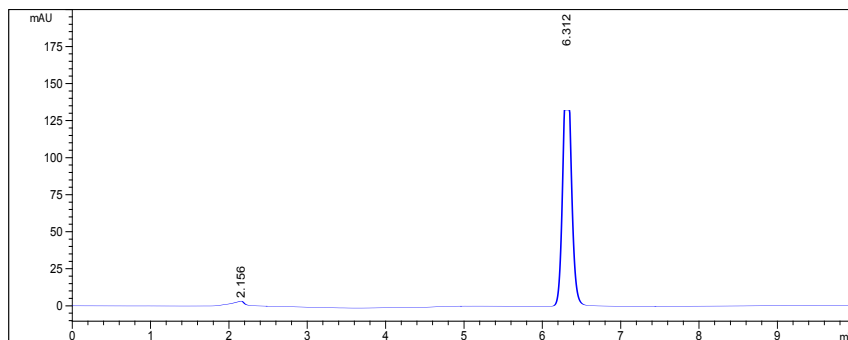
- Column: Agilent TC-C18 4.6×250 mm, 5 µm (518925-902)
- Mobile phase: methanol : water =7:93
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature : 30 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA069\009-0801



The chromatogram of the test solution--- HPLC2\WA069\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Piracetam	4.84	1554.8	10741	/	1.11

# Piracetam and Sodium Chloride Injection

Piracetam(100386-200301) – Method number WA073

## Assay

Test solution: Dilute a quantity of the solution, accurately measured, with mobile phase to produce a solution of 0.1 mg of piracetam per mL as the test solution.

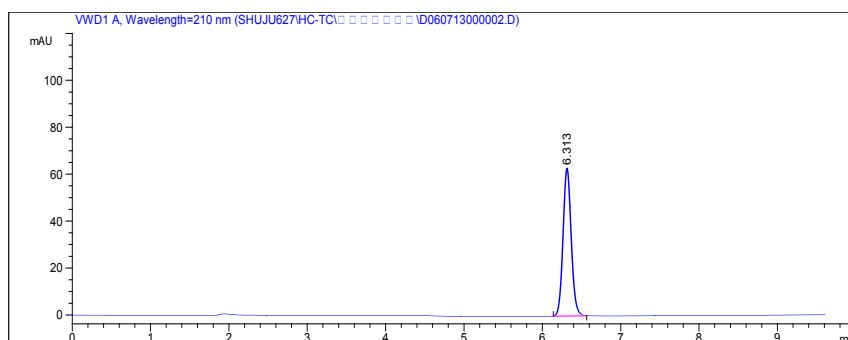
Reference solution: Repeat the procedure using piracetam CRS to produce the reference solution.

## Chromatographic conditions

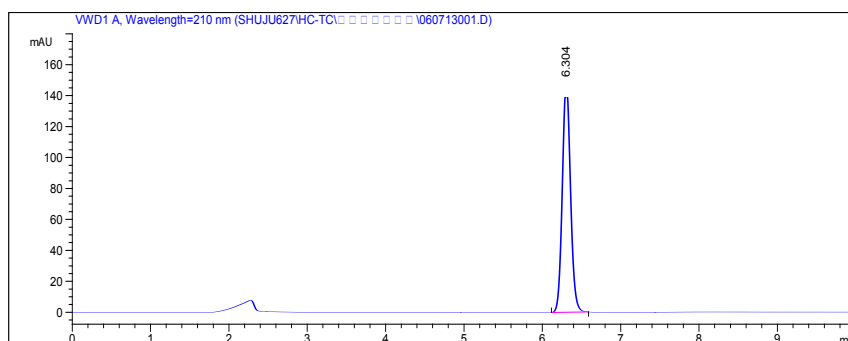
- Column: Agilent TC-C18 C18 4.6×250 mm, 5 µm (518925-902)
- Mobile phase: methanol : water =7:93
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature : 25 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA073



The chromatogram of the test solution--- HPLC2WA073

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Piracetam	6.304	1086.4	18057	/	1.09

# Piracetam Tablets – 吡拉西坦片

Piracetam(100386-200301) – Method number WA070

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to about 0.1 g of piracetam, in mobile phase in a 100 mL volumetric flask, shake to dissolve the piracetam and dilute to volume, mix well and filter, accurately transfer 5 mL of the filtrate to a 50 mL volumetric flask and dilute with mobile phase to volume, mix well. Use as the test solution.

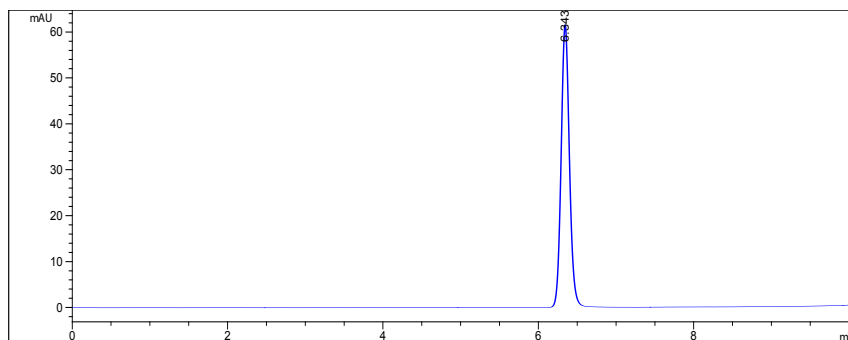
Reference solution: Repeat the procedure using piracetam CRS to produce the reference solution.

## Chromatographic conditions

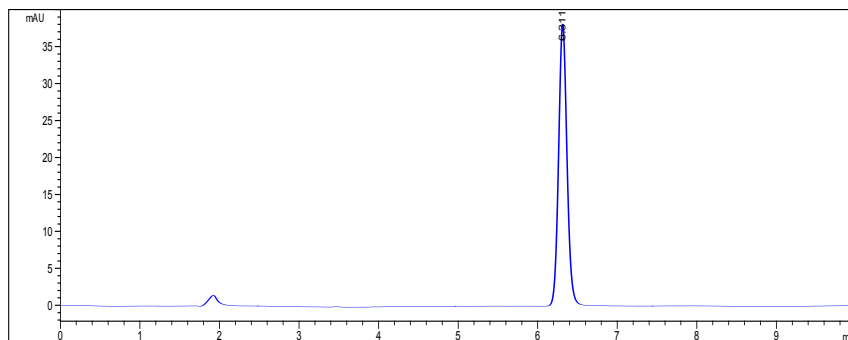
- Column: Agilent TC-C18 4.6×250 mm, 5 µm (518925-902)
- Mobile phase: methanol : water = 7:93
- Flow rate: 1.0 mL/min
- Injection volume: 3 µL
- Column temperature: 25 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA070001-0101



The chromatogram of the test solution--- HPLC2WA070002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Piracetam	6.311	277.9	18412	/	1.09



# Piracetam Injection – 吡拉西坦注射液

Piracetam (100386-200301) – Method number WA071

## Assay

Test solution: Dilute an accurately measured quantity of injection fluid with the mobile phase to produce a solution of 0.1 mg of piracetam per ml as the test solution.

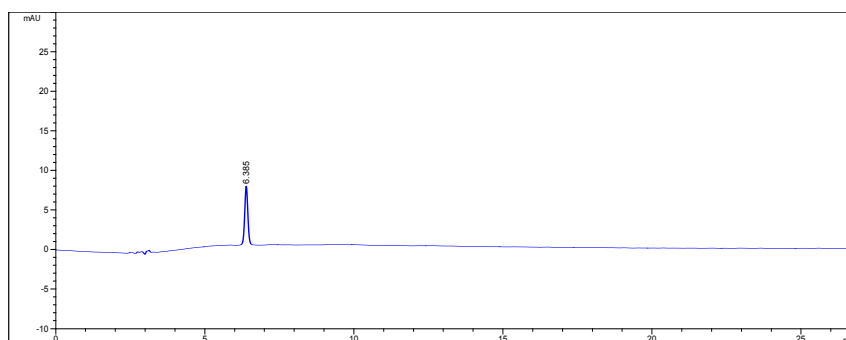
Reference solution: Repeat the procedure using piracetam CRS to produce the reference solution.

## Chromatographic conditions

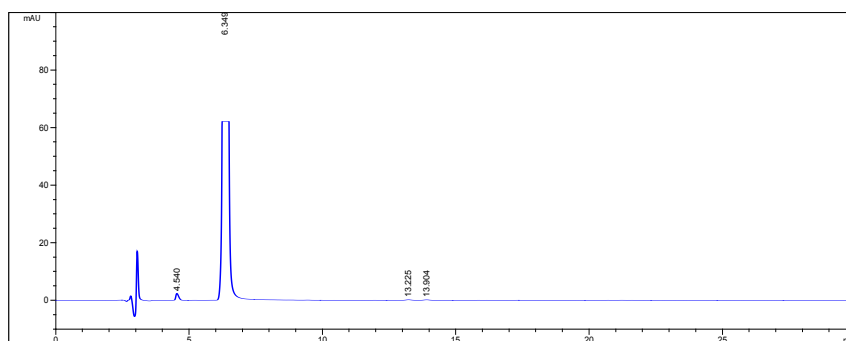
- Column: Agilent TC-C18 4.6×250 mm, 5 µm (518925-902)
- Mobile phase: methanol : water =7:93
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 25 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2



The chromatogram of the test solution--- HPLC2

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Piracetam	4.85	1669.3	10748	/	1.13

# Piracetam Injection – 吡拉西坦注射液

Piracetam (100386-200301) – Method number WA071

## Assay

Test solution: Prepare a solution of 0.5 mg piracetam per mL mobile phase.

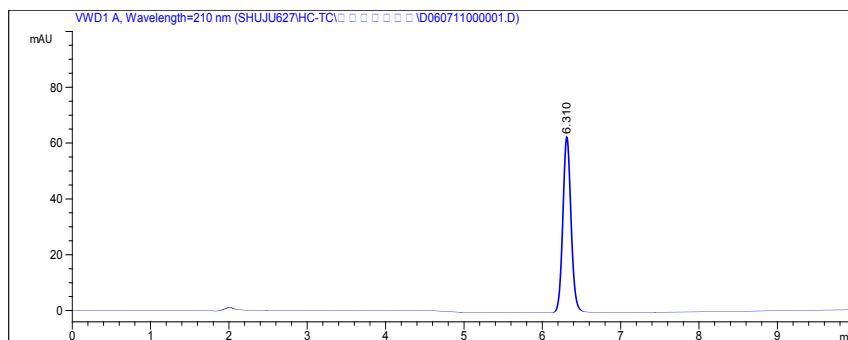
Reference solution: Prepare a solution of 5 µg of piracetam CRS per mL mobile phase.

## Chromatographic conditions

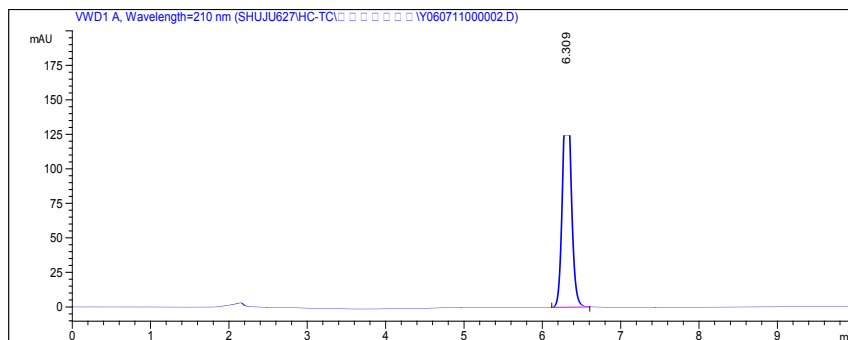
- Column: Agilent TC-C18 C18 4.6×250 mm, 5 µm (518925-902)
- Mobile phase: methanol : water =7:93
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature : 25 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA069\002-0201



The chromatogram of the test solution--- HPLC2\ WA069\008-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Piracetam	4.84	7000.2	10409	11.33	1.14
Impurity	3.11	9.1	11585	/	/

# Testosterone Propionate – 丙酸睾酮

Testosterone Propionate (0008-9404) – Method number WA006

## Assay

Internal standard solution: Dissolve a quantity of nandrolone phenylpropionate CRS, accurately weighed, in methanol to produce a solution of 1.6 mg/mL.

Test solution: Dissolve a quantity of testosterone propionate CRS in methanol to produce a solution of 1 mg/mL, use as the test solution.

Reference solution: Transfer 1 ml of the test solution, accurately measured, into a 100 mL volumetric flask, dilute with methanol to volume and mix well, use as the reference solution.

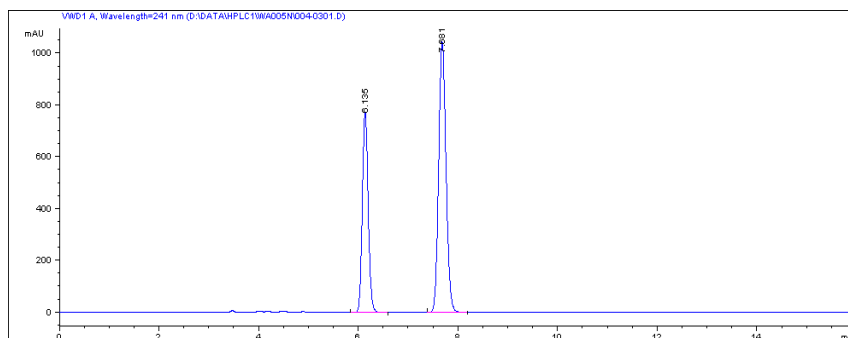
Dissolve a quantity of the substance, accurately weighed, in methanol in a 25 mL volumetric flask and dilute to volume, mix well. Accurately measure and transfer 5 mL each of this solution and the internal standard solution to a 25 mL volumetric flask, dilute with methanol to volume, mix well and use for the system suitability test.

## Chromatographic conditions

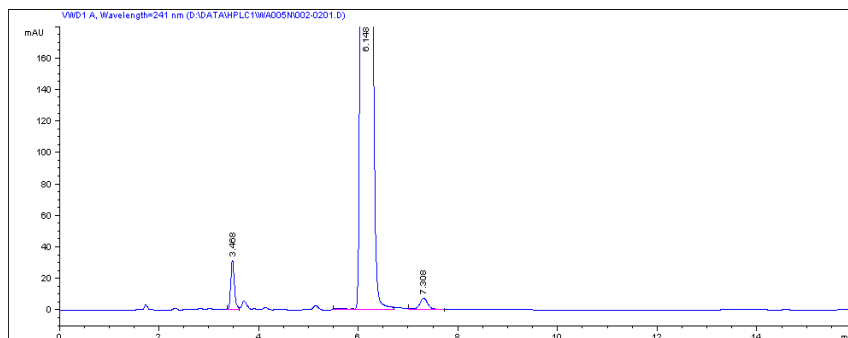
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : water = 90 : 10
- Column temperature: 30 °C
- Detector wavelength: 241 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the system suitability test---HPLC2WA005N004-0301



The chromatogram of the test solution --- HPLC2WA005N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Testosterone Propionate	6.14	6326.1	13093		1.08
Nandrolone Phenylpropionate	7.68	10794.9	12743	6.3	1.08

# Clobetasol Propionate – 丙酸氯倍他索

Clobetasol Propionate (10302-0001) – Method number WR005

## Assay

**Internal standard solution:** Add methanol to a quantity of fluocinonide to produce a solution of 0.15 mg/mL.

**Reference solution:** Dissolve an accurately weighed quantity of clobetasol propionate CRS in methanol and dilute to volume to produce a solution of 0.2 mg/mL. Accurately measure 5 mL of this solution and 5 mL of the internal standard solution in 50 mL volumetric flask, dilute to volume with methanol, mix well.

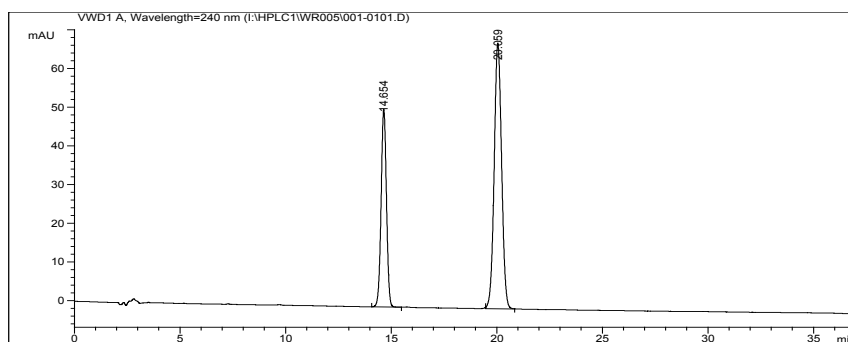
**Test solution:** Accurately weigh a quantity equivalent to about 1 mg of clobetasol propionate in a 50 mL volumetric flask, accurately add 5 mL of internal standard solution. Add 30 mL of methanol, heat in a water bath at 60 °C for 5 minutes, with intermittent stirring until the cream is completely dissolved, allow to cool, dilute to volume with methanol, mix well, cool in ice-water bath for more than 2 hours, filter immediately and cool to room temperature. Use the filtrate as test solution.

## Chromatographic conditions

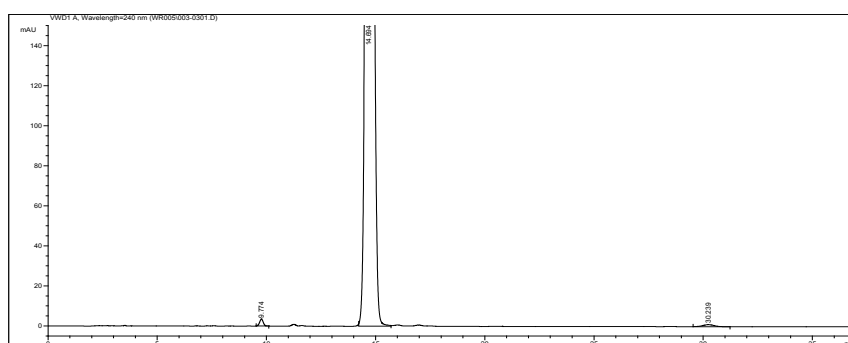
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.05 mol/L sodium dihydrogen phosphate solution (adjust pH to 2.5 with 85 % phosphoric acid solution) : acetonitrile : methanol = 425:475:100
- Column temperature: 30 °C
- Detector wavelength: 240 nm
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability --- HPLC1\WR005\001-0101.D



The chromatogram of the test solution --- HPLC1\WR005\003-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clobetasol Propionate	14.66	898.6	15826	/	0.99
Beclometasone Dipropionate	20.06	1678.7	15750	9.8	1.02

# Clobetasol Propionate Cream – 丙酸氯倍他索乳膏

Clobetasol Propionate (10302-0001) – Method number WA005

## Assay

**Internal standard solution:** Add methanol to a quantity of fluocinonide to produce a solution of 0.15 mg/mL.

**Reference solution:** Dissolve an accurately weighed quantity of clobetasol propionate CRS in methanol and dilute to volume to produce a solution of 0.2 mg/mL. Accurately measure 5 mL of this solution and 5 mL of the internal standard solution in 50 mL volumetric flask, dilute to volume with methanol, mix well.

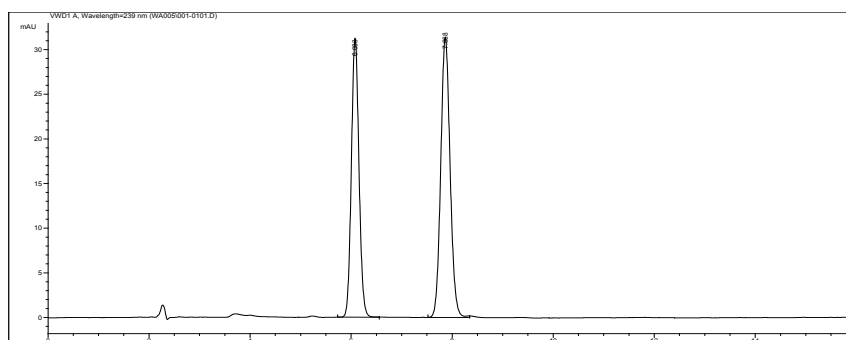
**Test solution:** Accurately weigh a quantity equivalent to about 1 mg of clobetasol propionate in a 50 mL volumetric flask, accurately add 5 mL of internal standard solution. Add 30 mL of methanol, heat in a water bath at 60 °C for 5 minutes, with intermittent stirring until the cream is completely dissolved, allow to cool, dilute to volume with methanol, mix well, cool in ice-water bath for more than 2 hours, filter immediately and cool to room temperature. Use the filtrate as test solution.

## Chromatographic conditions

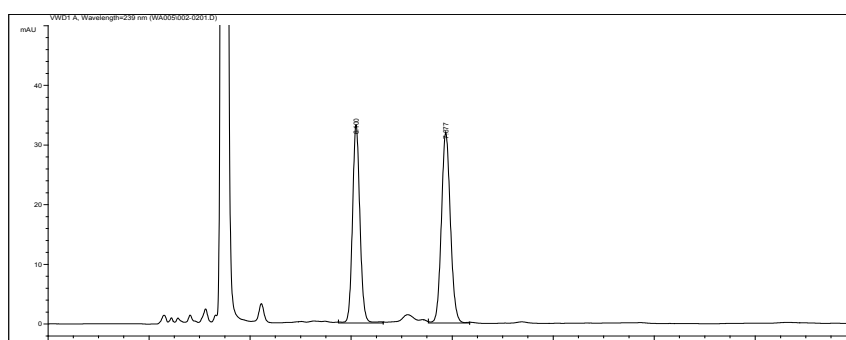
- Column: Agilent ZORBAX Eclipse XDB C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : water = 75:25
- Column temperature: 30 °C
- Detector wavelength: 239nm
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of chemical reference substance ---HPLC2WA005001-0101



The chromatogram of test solution ---HPLC2WA005002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Fluocinolone Acetonide	6.10	335.1	8375		1.07
Clobetasol Propionat	7.88	394.0	9591	6.02	1.07

# Ibuprofen Drops – 布洛芬滴剂

Ibuprofen (100179-200303) – Method number WA243

## Assay

Test solution: Accurately transfer 2 mL of the drops, thoroughly shaken, to a 100 mL volumetric flask, dilute with 50 % methanol to volume, mix well and filter, use the filtrate as the test solution.

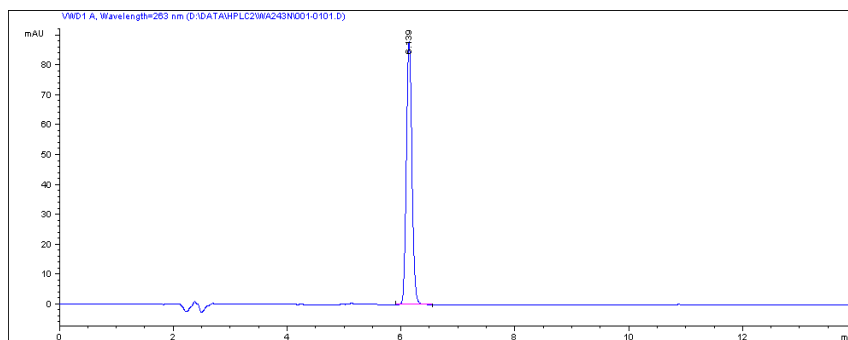
Reference solution: Repeat the operation, using ibuprofen CRS to produce reference solution of 0.8 mg/mL.

## Chromatographic conditions

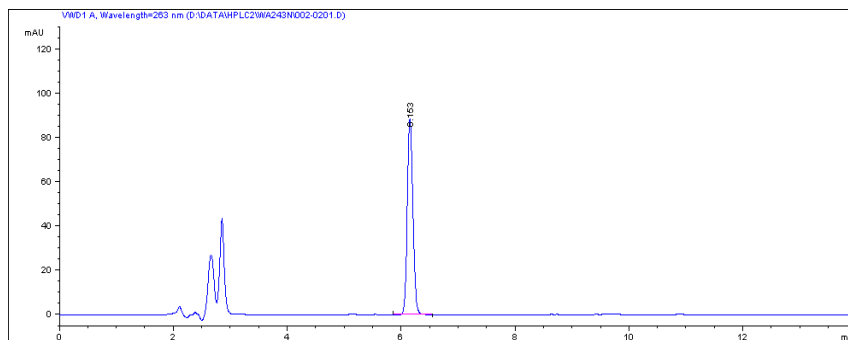
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm
- (880975-902)
- Mobile phase: sodium acetate BS (dissolve 6.13 g of sodium acetate in 750 mL of water, by shaking, adjust pH to 2.5 with glacial acetic acid) : acetonitrile = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 263 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA243N001-0101



The chromatogram of the test solution --- HPLC2WA243N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ibuprofen	6.15	602.7	15479	/	1.05

# Ibuprofen Oral Solution – 布洛芬口服溶液

Ibuprofen (100179-200303) – Method number WA018

## Assay

Test solution: Accurately transfer a quantity of the solution with a pipette, dilute with methanol to produce a solution of 0.5 mg/mL.

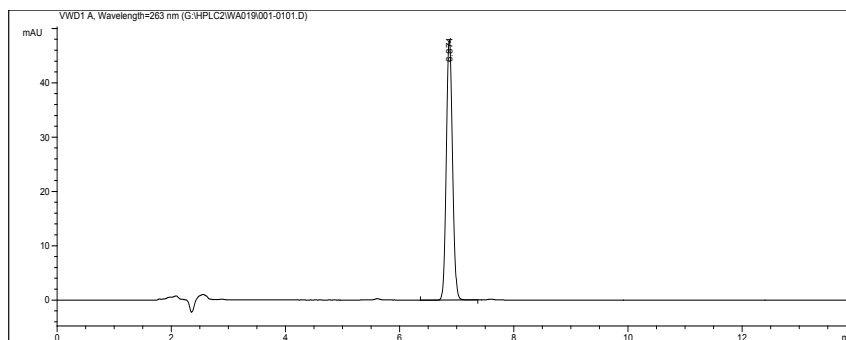
Reference solution: Prepare a solution of 0.5 mg of ibuprofen CRS per mL in methanol.

## Chromatographic conditions

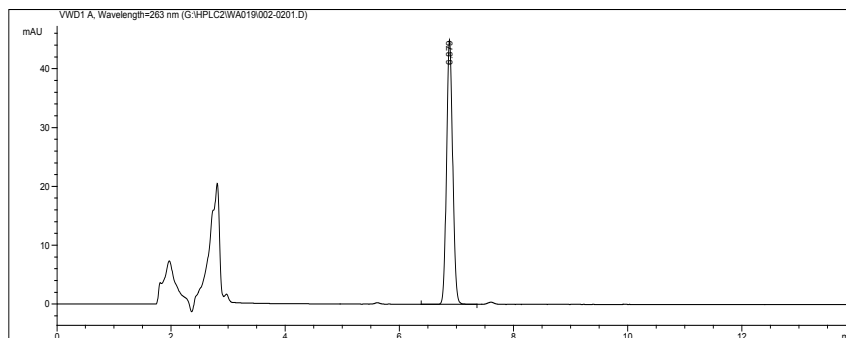
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium acetate BS (dissolve 6.13g of sodium acetate in 750 mL of water, by shaking, adjust to pH 2.5 with glacial acetic acid) : acetonitrile = 40:60
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 263 nm
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA019\001-0101



The chromatogram of the test solution --- HPLC2\WA019\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ibuprofen	6.88	335.9	18806	/	1.05

# Ibuprofen Syrup – 布洛芬糖浆

Ibuprofen (100179-200303) – Method number WA019

## Assay

Test solution: Accurately transfer a quantity of the solution with a pipette, dilute with methanol to produce a solution of 0.5 mg/mL.

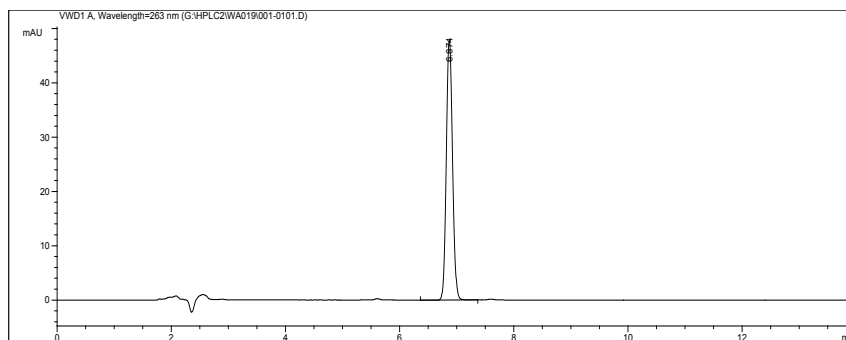
Reference solution: Prepare a solution of 0.5 mg of ibuprofen CRS per mL in methanol.

## Chromatographic conditions

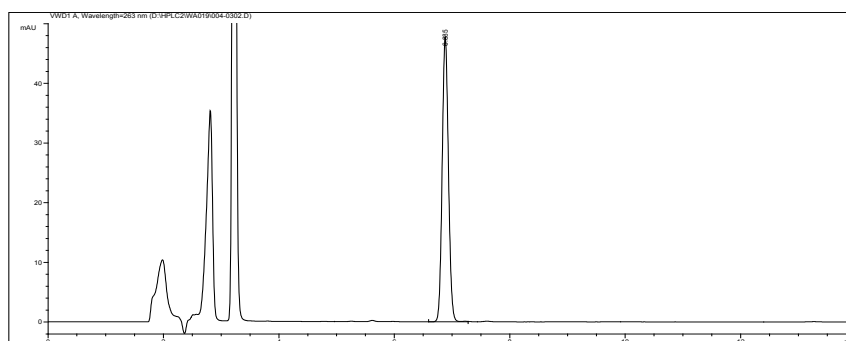
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium acetate BS (dissolve 6.13 g of sodium acetate in 750 mL of water, by shaking, adjust to pH 2.5 with glacial acetic acid) : acetonitrile = 40:60
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 263 nm
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA019\001-0101



The chromatogram of the test solution --- HPLC2\WA019\004-0302

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ibuprofen	6.88	358.3	19354	/	1.05



# Ibuprofen and Pseudoephedrine Hydrochloride Tablets

Ibuprofen (100179-200303)

Pseudoephedrine hydrochloride (171237-200304) – Method number WA239

布洛伪麻片

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to 100 mg of ibuprofen and 15 mg of pseudoephedrine hydrochloride, in methanol in a 50 mL volumetric flask and dilute to volume, mix well. Filter and accurately transfer 5 mL of the filtrate to a 50 mL volumetric flask, dilute with methanol to volume, mix well and use as the test solution.

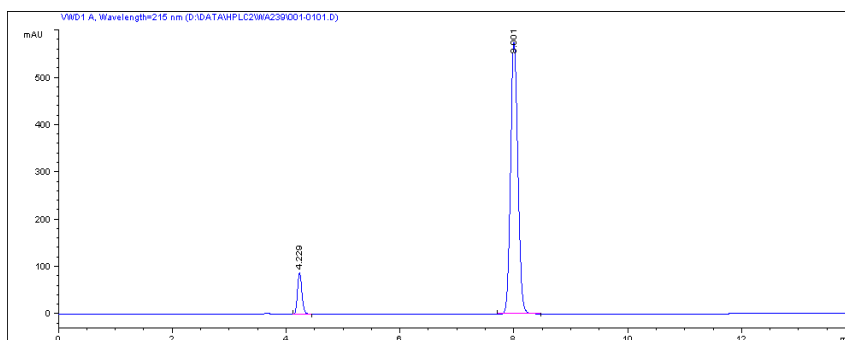
Reference solution: Dissolve a quantity of ibuprofen CRS and pseudoephedrine hydrochloride CRS, equivalent to the concentrations in the test solution, in methanol to produce the reference solution.

## Chromatographic conditions

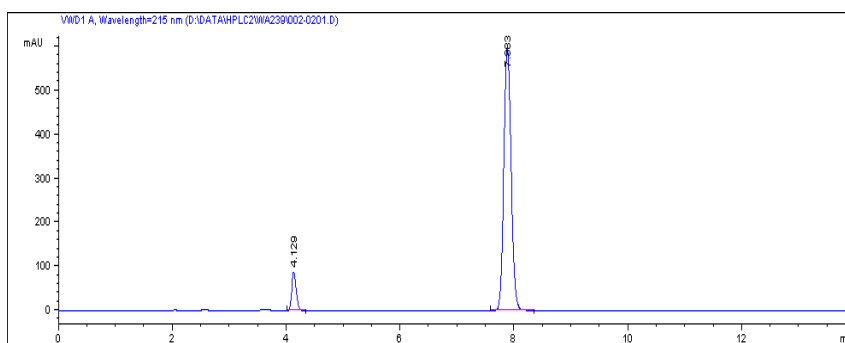
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: phosphate BS (dissolve 0.68 g of sodium dodecyl sulfonate in a mixture of 250 mL of acetonitrile and 250 mL of 0.02 mol/L potassium dihydrogen phosphate, adjust pH to 3.5 with phosphoric acid) : methanol = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA239\001-0101



The chromatogram of the test solution --- HPLC2\WA239\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>i</sub>
Pseudoephedrine Hydrochloride	4.13	480.5	13244	/	1.19
Ibuprofen	7.88	5322.9	17785	19.7	1.06

# Bulleyaconitine A – 草乌甲素

## Bulleyaconitine A – Method number WA135

### Assay

Test solution: Dissolve a quantity of the substance, accurately weighed, in mobile phase to produce a solution of 0.2 mg/mL as the test solution.

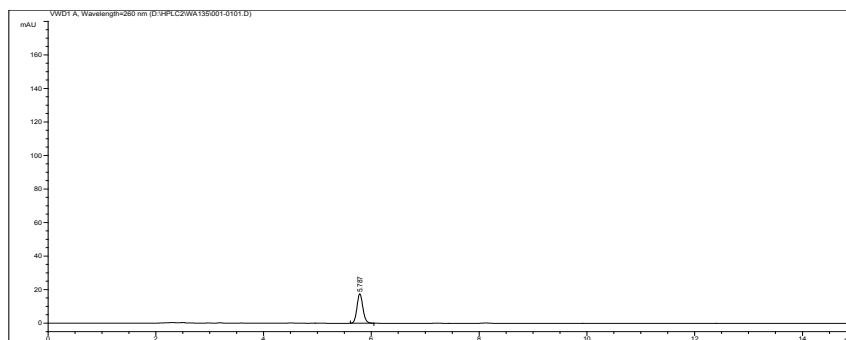
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce a solution of 4 µg/mL as the reference solution.

### Chromatographic conditions

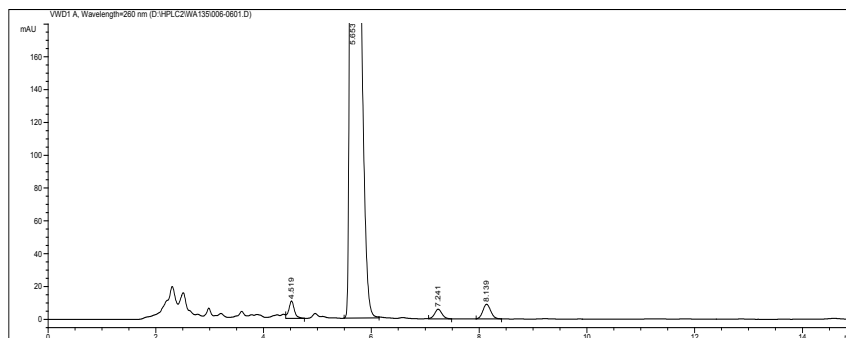
- Column : Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile : 0.2 % triethylamine solution (adjust pH to 3.1±0.1 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 260 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA135\002-0201



The chromatogram of the test solution--- HPLC2\WA135\006-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Bulleyaconitine A	5.65	6499.3	4874	4.6	1.48
Impurity1	4.52	86.9	9922	/	/
Impurity2	7.24	64.3	12566	5.3	0.96
Impurity3	8.14	96.9	14319	3.4	1.08

# Bulleyaconitine A Oral Solution – 草乌甲素口服液

Bulleyaconitine A – Method number WA136

## Assay

Test solution: Dilute an accurately measured quantity of the substance with mobile phase to produce a solution of 20 µg/mL as the test solution.

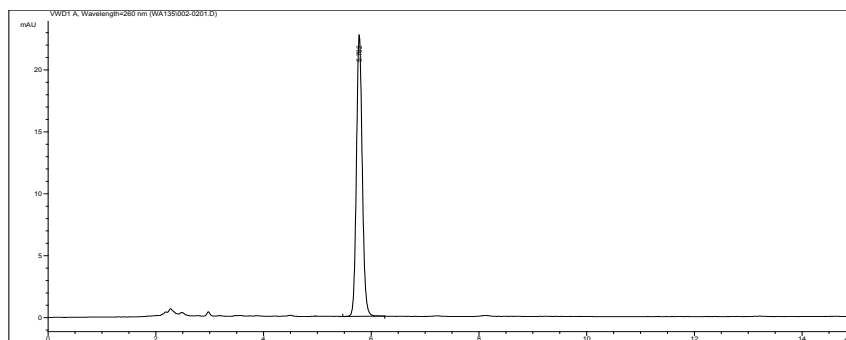
Reference solution: Dissolve and dilute an accurately weighed quantity of bulleyaconitine A CRS with mobile phase to produce a solution of 20 µg/mL as the reference solution.

## Chromatographic conditions

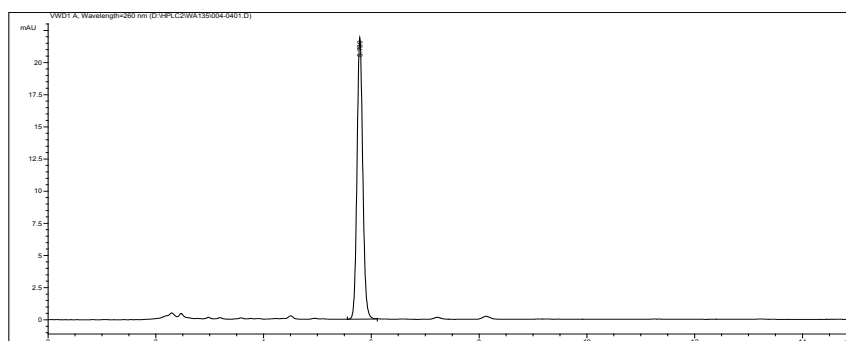
- Column : Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile : 0.2 % triethylamine solution (adjust pH to 3.1±0.1 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 260 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA135\002-0201



The chromatogram of the test solution--- HPLC2\WA135\004-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Bulleyaconitine A	5.79	162.8	13310	/	1.07

# Potassium Dehydroandrograpolid Succinate – 穿琥宁

Potassium dehydroandrograpolid succinate (111598-200301) – Method number WA131

## Assay

Test solution: Dissolve an accurately measured quantity of the substance in mobile phase to produce a solution of 0.4 mg/mL as the test solution.

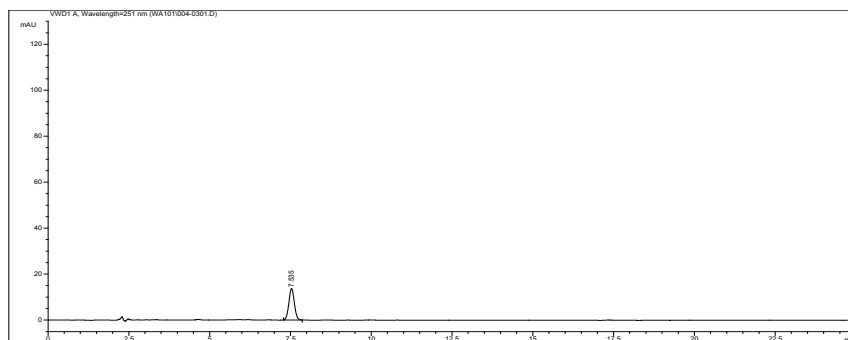
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce a solution of 8 µg/mL as the reference solution.

## Chromatographic conditions

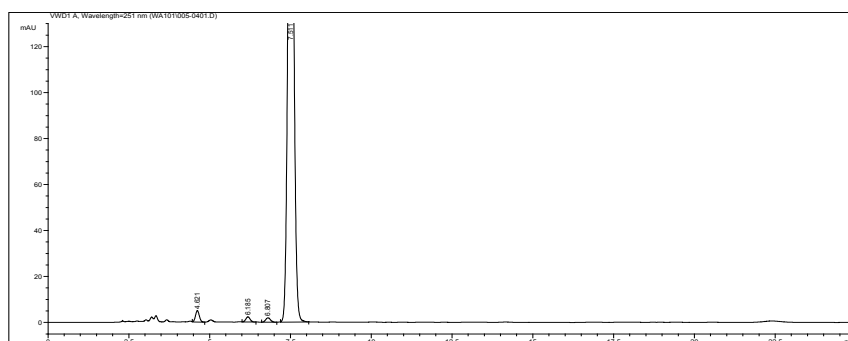
- Column : Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : 0.05 % potassium dihydrogen phosphate solution (adjust to pH 2.5±0.05 to with phosphoric acid) = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 251 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA101\004-0301



The chromatogram of the test solution --- HPLC1\ WA101\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>i</sub>
Dehydroandrograpolid Succinate	7.51	3314.6	9519	2.5	1.05
Impurity1	4.62	41.1	7428	/	1.01
Impurity2	6.19	20.7	10697	6.9	1.03
Impurity3	6.81	18.9	10641	2.5	1.04

# Estradiol – 雌二醇

Estradiol (10182-0103) – Method number WR125

## Assay

Test solution: Dissolve an accurately measured quantity of the substance in mobile phase to produce a solution of 1 mg/mL as the test solution.

Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce a solution of 10 µg/mL as the reference solution.

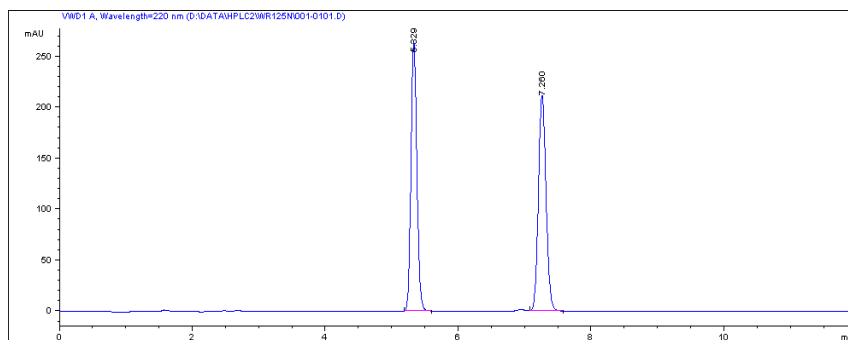
Dissolve a quantity of estradiol and estrone in mobile phase to produce a solution of 0.1 mg/mL each for the system suitability test.

## Chromatographic conditions

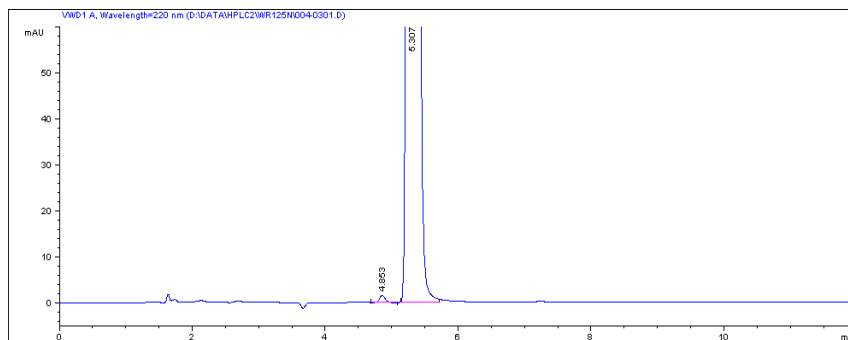
- Column: Agilent ZORBAX Bonus-RP, 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetonitrile:water=55:45
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2WR125N001-0101



The chromatogram of the test solution --- HPLC2WR125N004-0301

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Estradiol	5.33	1645.9	16172	/	1.07
Estrone	7.26	1684.2	18337	10.1	1.09

# Estradiol Sustained-release Patch – 雌二醇缓释贴片

Estradiol (10182-0103) – Method number WA222

## Assay

Test solution: Remove the protective liner from one patch and put in a 100 mL volumetric flask, allow the patch to soak in 5 mL of ethyl acetate for 30 minutes, place the volumetric flask in an ultrasonic bath for 15 minutes to dissolve the estradiol, allow to cool to room temperature, dilute with methanol to volume, mix well and filter, use the filtrate as the test solution.

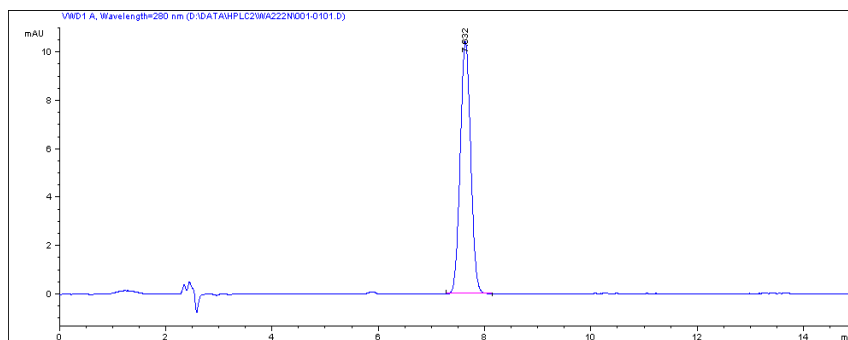
Reference solution: Dissolve an accurately weighed quantity of estradiol CRS in methanol to produce a reference solution of about 25 µg/mL.

## Chromatographic conditions

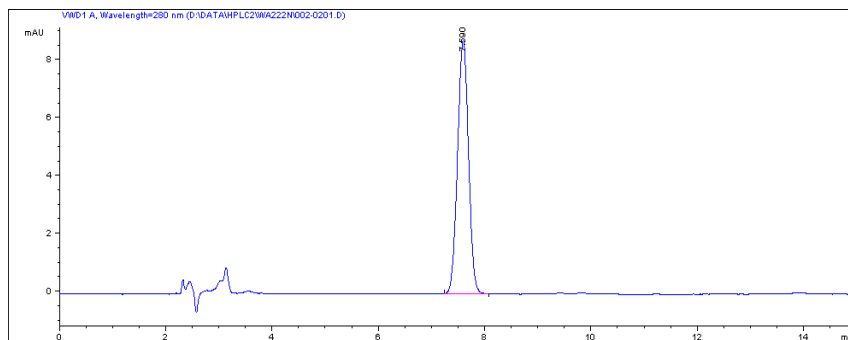
- Column: Agilent ZORBAX Bonus-RP, 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: methanol:water=75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA222N001-0101



The chromatogram of the test solution--- HPLC2WA222N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Estradiol	7.59	125.5	6133	/	1.00

# Dexamethasone Acetate – 醋酸地塞米松

Hydrocortisone acetate (10013-0106) Dexamethasone acetate (100122-200304) –  
Method number WR127

## Assay

Test solution: Dissolve about 25 mg of the substance in 17 mL methanol in a 25 mL volumetric flask, dilute with sodium acetate solution (pH 4.5) to volume, mix well and use as the test solution.

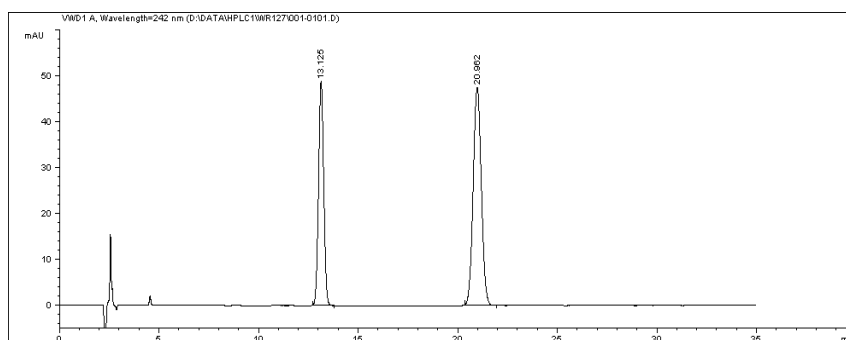
Reference solution: Dissolve about 10 mg of hydrocortisone acetate with 7 mL of methanol in a 10 mL volumetric flask and dilute with sodium acetate solution (pH 4.5) to volume, mix well. Accurately measure 1 mL each of the resulting solution and test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

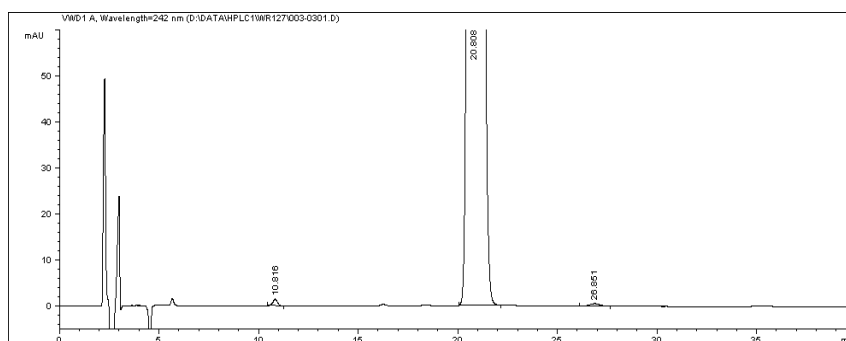
- Column: Agilent ZORBAX SB-C18, 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : tetrahydrofuran : sodium acetate solution (dissolve 10.2 g of sodium acetate in water and dilute to 1000 mL, mix well, adjust pH to 4.5±0.05 with glacial acetic acid) = 30:10:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 242 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC1\WR127\001-0101.D



The chromatogram of the test solution --- HPLC1\WR127\003-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dexamethasone Acetate	13.13	885.0	12044	/	1.04
Hydrocortisone acetate	20.96	1353.1	12759	12.8	1.04

# Dexamethasone Acetate Tablets – 醋酸地塞米松片

Dexamethasone acetate (100122-200304) – Method number WR128

## Assay

Test solution; Accurately weigh 20 tablets and grind to a fine powder. To an accurately weighed quantity, equivalent to about 2.5 mg of dexamethasone acetate, add a quantity of mobile phase in a 50 mL volumetric flask, treat ultrasonically for 30 minutes until the dexamethasone acetate dissolves. Dilute with mobile phase to volume, shake well and filter, use the filtrate as the test solution.

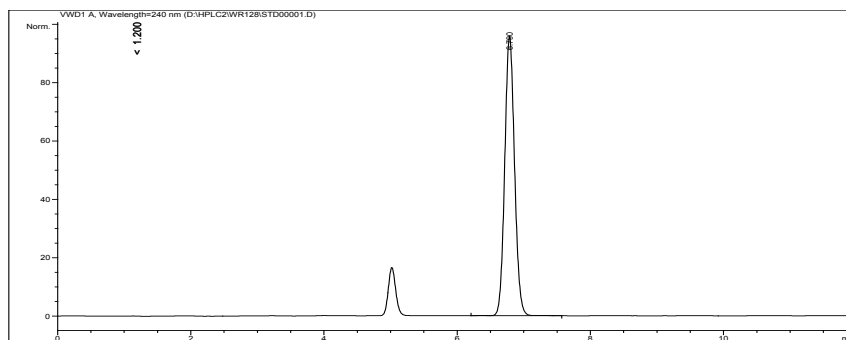
Reference solution: Dissolve a quantity of dexamethasone acetate CRS in mobile phase to produce a solution of 50 µg/mL as the reference solution.

## Chromatographic conditions

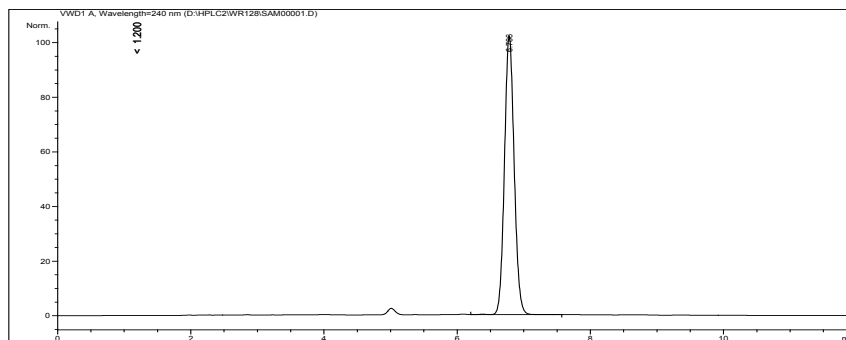
- Column: Agilent ZORBAX Eclipse XDB C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:water = 70:30
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR128\STD00001



The chromatogram of the test solution ---HPLC2\WR128\SAM00001

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dexamethasone Acetate	6.79	1033.8	9651	/	1.05



# Dexamethasone Acetate Ointment – 醋酸地塞米松软膏

Dexamethasone acetate (100122-200304) – Method number WR129

## Assay

Test solution: Dissolve an accurately weighed quantity of the cream, equivalent to about 0.5mg of dexamethasone acetate, in 50 mL of methanol, mix for 30 seconds at 9500 rpm with a homogenizer, put in an ice-water bath for 1 hour, filter through a millipore membrane (0.45 µm), discard the first 5 mL and use the successive filtrate as the test solution.

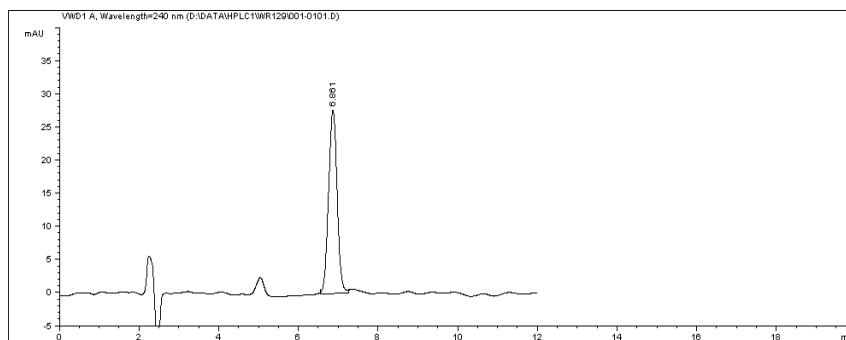
Reference solution: Dissolve an accurately weighed quantity of dexamethasone acetate CRS in methanol and dilute to produce a solution of 10 µg/mL as the reference solution.

## Chromatographic conditions

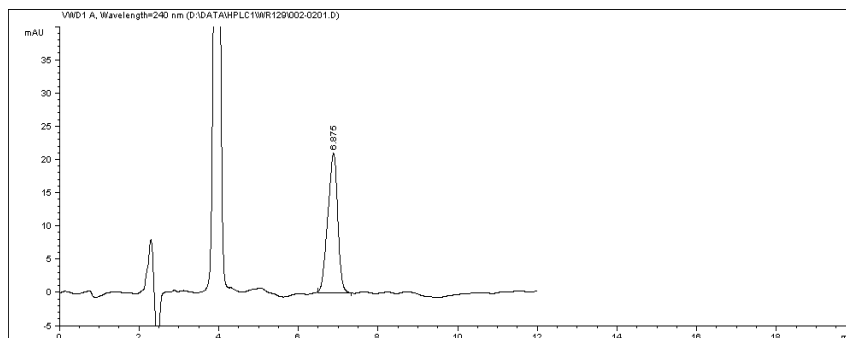
- Column: Agilent ZORBAX Eclipse XDB C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:water = 70:30
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR129\001-0101



The chromatogram of the test solution --- HPLC1\WR129\002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dexamethasone Acetate	6.87	364.2	3542	/	0.95

# Megestrol Acetate Tablets – 醋酸甲地孕酮片

Megestrol acetate (10171-0102) – Method number WA224

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. To an accurately weighed quantity, equivalent to about 1 mg of megestrol acetate, add a quantity of methanol in a 50 mL volumetric flask, and treat ultrasonically until the megestrol acetate dissolves, dilute with methanol to volume, mix well and centrifuge, use the supernatant as the test solution.

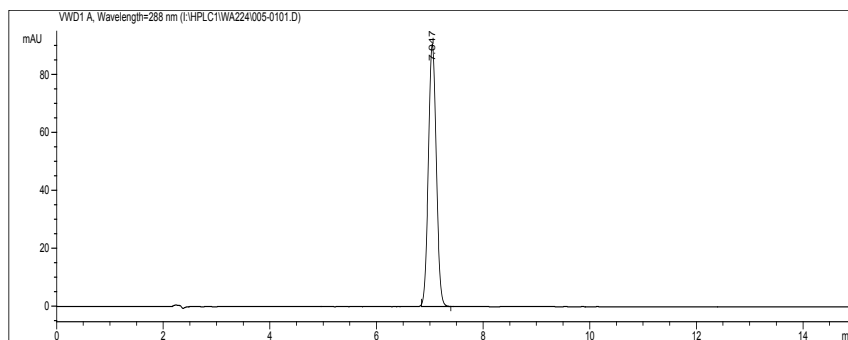
Reference solution: Dissolve an accurately weighed quantity of megestrol acetate CRS in methanol to produce a solution of about 20 µg/mL as the reference solution.

## Chromatographic conditions

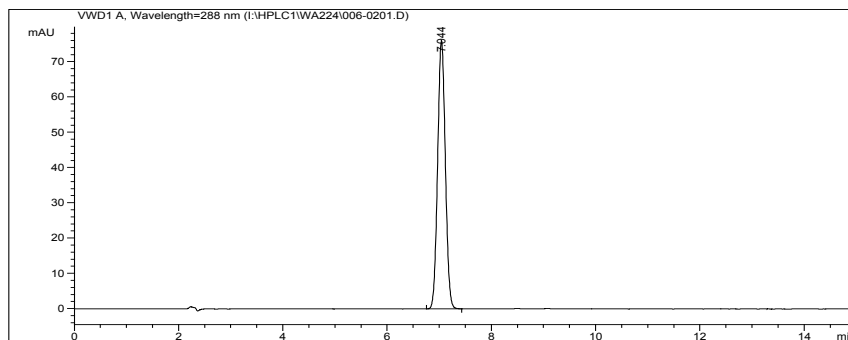
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water:methanol = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 288 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA224\005-0101.D



The chromatogram of the test solution--- HPLC1\WA224\006-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Megestrol Acetate	7.04	782.6	10090	/	1.05

# Cortisone Acetate – 醋酸可的松

Cortisone acetate (100123-200303) Hydrocortisone acetate (10013-0106) – Method number WR126

## Assay

Test solution: Accurately weigh about 10 mg in a 10 mL volumetric flask, add a quantity of acetonitrile, shake to dissolve the cortisone acetate and dilute to volume, mix well and use as the test solution.

Reference solution: Dilute an accurately measured quantity of the test solution with acetonitrile to produce a solution of 10 µg/mL as the reference solution.

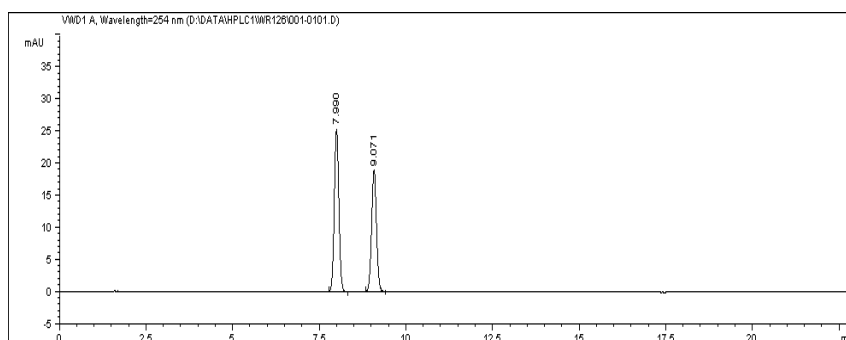
Dissolve an accurately weighed quantity of cortisone acetate CRS and hydrocortisone acetate CRS in acetonitrile to produce a mixture of 10 µg/mL each for the system suitability test.

## Chromatographic conditions

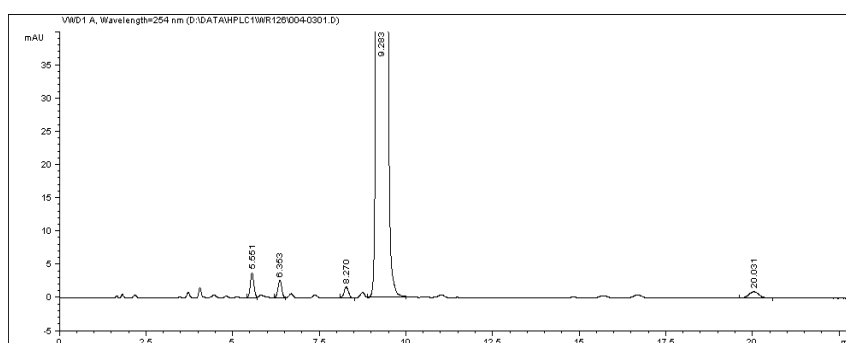
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile:water = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC\WR126\001-0101.D



The chromatogram of the test solution --- HPLC\WR126\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cortisone Acetate	9.07	189.0	19711	4.3	1.04
Hydrocortisone Acetate	7.99	233.5	17854	/	1.03

# Hydrocortisone Acetate – 醋酸氢化可的松

Hydrocortisone acetate (10013-0106) – Method number WR201

## Assay

Test solution: Dissolve about 17 mg of the substance in 20 mL of ethanol in a 50 mL volumetric flask and treat ultrasonically until the hydrocortisone acetate dissolves, dilute with water to volume, mix well and use as the test solution.

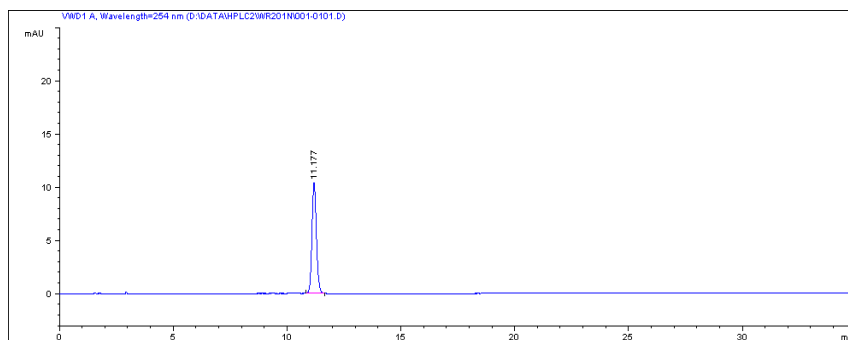
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

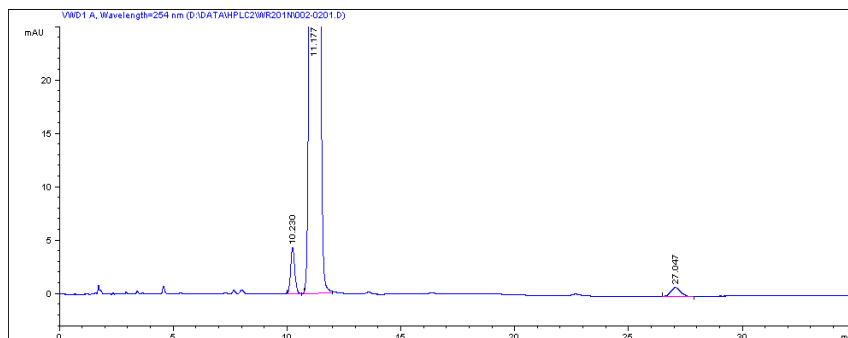
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: water: acetonitrile = 62: 38
- Flow rate: 1 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR201N\001-0101.D



The chromatogram of the test solution --- HPLC2\WR201N\002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Hydrocortisone Acetate	11.18	15438.2	16274	2.8	1.09
Impurity1	10.23	53.4	16193	/	1.09
Impurity2	27.05	25.4	19067	27.9	1.06

# Rifampicin for Eye Use – 滴眼用利福平

Rifampicin (130496-2000010)

Rifampicin quinone (130413-200303) – Method number WA221

## Assay

Test solution: Accurately weigh a quantity of the substance and grind to a fine powder. To an accurately weighed quantity of the powder add 30 mL of a mixture of acetonitrile-water (6:4) in a 50 mL volumetric flask, treat ultrasonically for 2 minutes to dissolve the rifampicin, dilute to volume, mix well and filter. Accurately transfer 5 mL of the filtrate to a 25 mL volumetric flask, dilute with a mixture of acetonitrile-water (6:4) to volume and mix well.

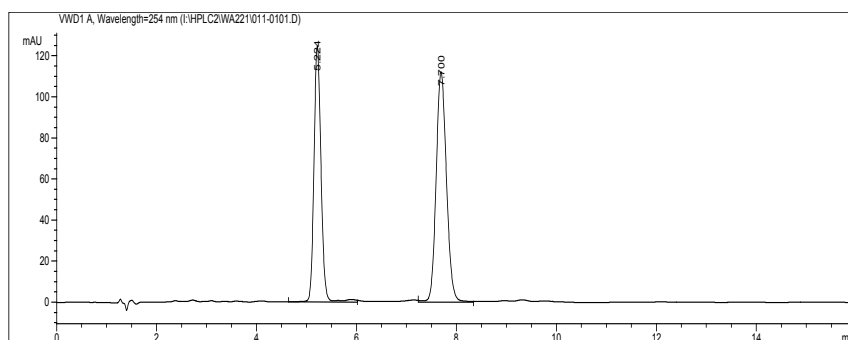
Dissolve a quantity of rifampicin CRS and rifampicin quinone CRS in a mixture of acetonitrile-water (6:4) to produce a solution of 0.08 mg/mL for the system suitability test.

## Chromatographic conditions

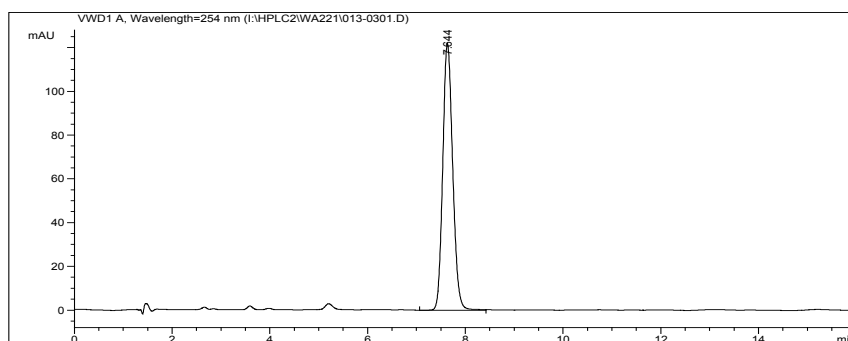
- Column: Agilent ZORBAX XDB-C8 4.6×150 mm, 5 µm (993967-906)
- Mobile phase: 75 mM potassium dihydrogen phosphate : 1 M citric acid : methanol : acetonitrile = 40:4:28:28
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2\WA221\001-0101.D



The chromatogram of the test solution --- HPLC2\WA221\013-0301

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Rifampicin	7.70	1575.7	6309	7.6	1.09
Rifampicin quinone	5.22	1189.7	6266	/	1.07

# Digoxin – 地高辛

Digoxin (10015-200308)– Method number WA039

## Assay

Test solution: Dissolve a quantity of the substance in dilute ethanol to produce a solution of 1 mg/mL as the test solution.

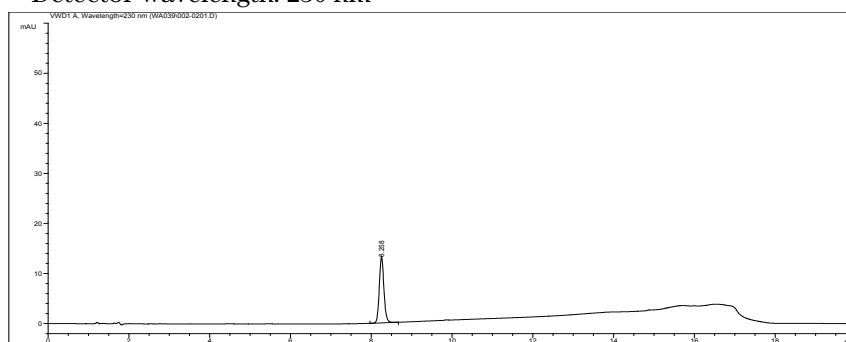
Reference solution: Dilute an accurately measured quantity of the test solution with dilute methanol to produce a solution of 0.02 mg/mL as the reference solution.

## Chromatographic conditions

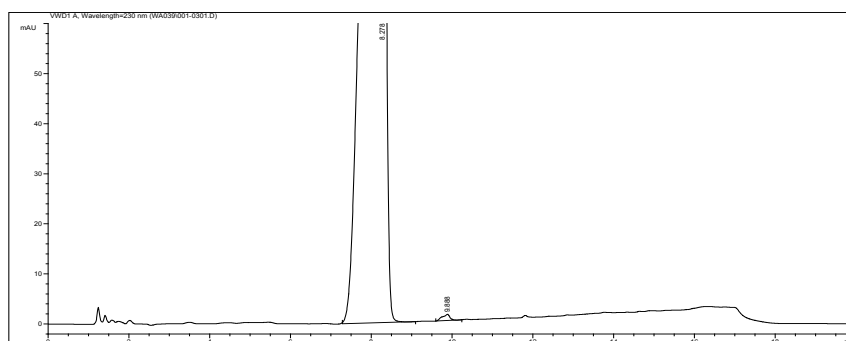
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: a mixture of acetonitrile-water (10:90) as the mobile phase A, a mixture of acetonitrile-water (60:40) as the mobile phase B. Gradient: 0 min, 35 %B; 5 min, 35 %B; 15 min, 100 %B; 15.1 min, 35 %B; 20 min, 35 %B.
- Flow rate: 1.5 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA039\002-0201



The chromatogram of the test solution--- HPLC1\WA039\001-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Digoxin	8.28	5228.3	1198	/	/
Impurity	9.89	16.0	11029	3.4	/

# Digoxin Tablets – 地高辛片

Digoxin(10015-0208) – Method number WA040

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder, accurately weigh a quantity of powder equivalent to about 2.5 mg of digoxin in a 25 mL volumetric flask, add a quantity of dilute ethanol. Treat ultrasonically for 30 minutes to dissolve the digoxin, dilute to volume with ethanol, mix well, filter through a millipore membrane (0.45 µm) and use as the test solution.

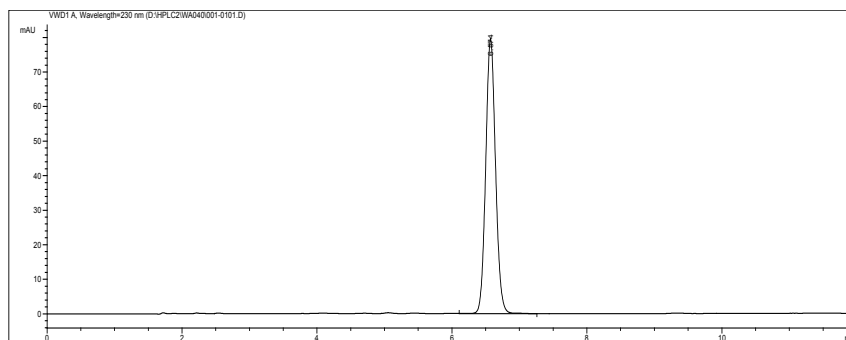
Reference solution: Dissolve an accurately weighed quantity of digoxin CRS in dilute ethanol to produce a solution of 0.1 mg/mL as the reference solution.

## Chromatographic conditions

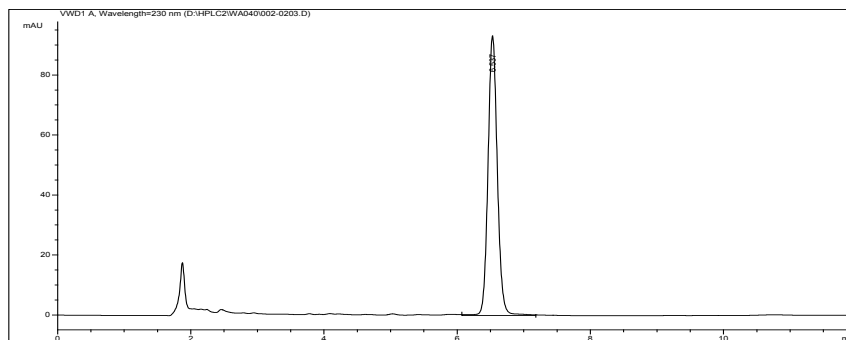
- Column : Agilent ZORBAX Eclipse XDB C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase : acetonitrile :water=32:68
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA040001-0101



The chromatogram of the test solution--- HPLC2WA040002-0203

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Digoxin	6.54	894.1	9612	/	1.06

# Dexamethasone Tablets – 地塞米松片

Dexamethasone (100129-200303) – Method number WA254

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Wet an accurately weighed quantity of the powder, equivalent to about 1.5 mg of dexamethasone, with 4 drops of methanol in a 50 mL volumetric flask, add mobile phase and treat ultrasonically to dissolve the dexamethasone, dilute with mobile phase to volume, mix well and filter, use the filtrate as test solution.

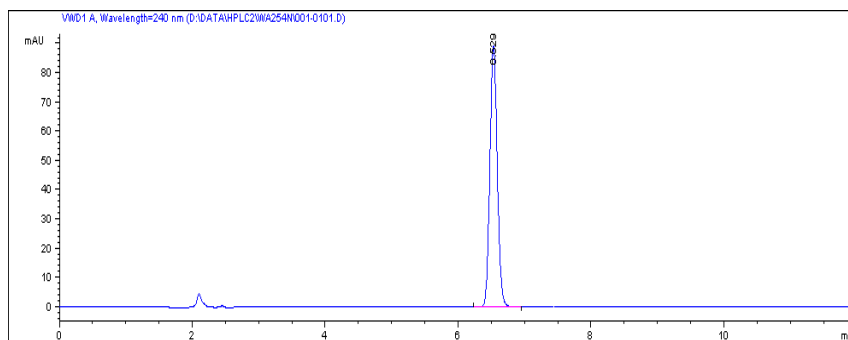
Reference solution: Accurately weigh about 15 mg of dexamethasone CRS, dissolve in mobile phase in a 50 mL volumetric flask, dilute to volume to produce a solution of about 30 µg/mL as the reference solution.

## Chromatographic conditions

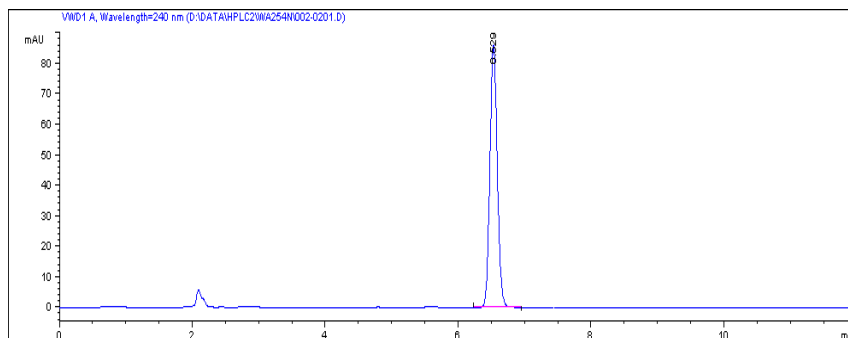
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile:water=40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC1\WA254N001-0101



The chromatogram of the test solution --- HPLC1\ WA254N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Dexamethasone	6.53	666.1	16043	/	1.07



# Dexamethasone – 地塞米松

Dexamethasone (100129-200303)

Methyl prednisolone (ARCOS) – Method number WR030

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution of about 0.5 mg/mL.

Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask and dilute to volume with mobile phase, mix well and use as the reference solution.

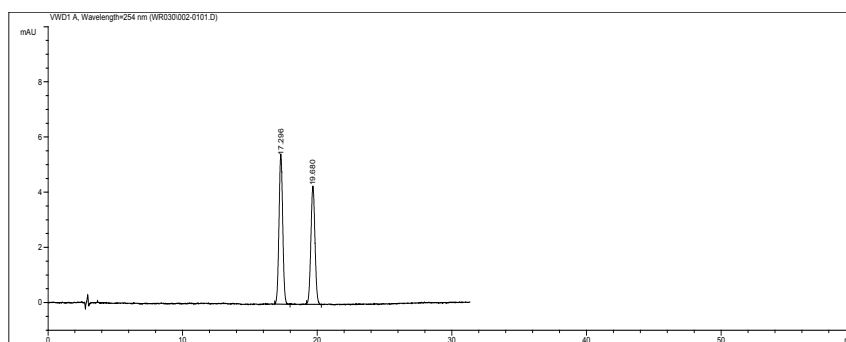
Dissolve a quantity of methylprednisolone CRS in the reference solution to make a solution of 5 µg/mL for the system suitability test.

## Chromatographic conditions

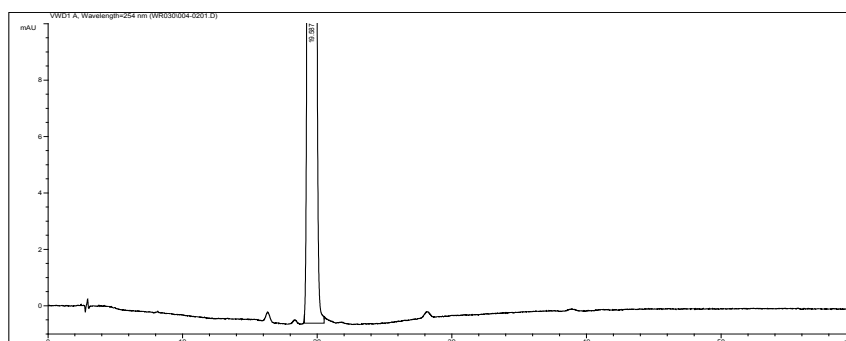
- Column: Agilent ZORBAX SB-Phenyl 4.6×250 mm, 5 µm (880975-912)
- Mobile phase: acetonitrile 0.02 mol/L ammonium formate solution (adjust pH to 3.6 with acetic acid) (30:70)
- Flow rate: 1.0 mL/min Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC1\WR030\002-0101



The chromatogram of the test solution --- HPLC1\ WR030\004-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP $T_r$
Methyl prednisolone	17.30	104.6	18014	/	1.03
Dexamethasone	Dexamethasone	90.6	19697	4.4	1.03

# Dexamethasone Sodium Phosphate – 地塞米松磷酸钠

Dexamethasone (100129-200303)

Dexamethasone sodium phosphate (10016-0011) – Method number WR151

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase to produce a solution of 1 mg/mL as the test solution.

Reference solution: Dissolve an accurately weighed quantity of dexamethasone CRS in methanol to produce a solution of 1 mg/mL as the reference solution.

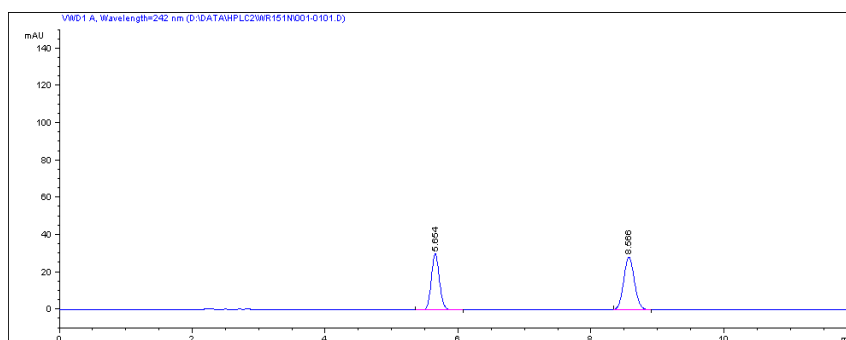
Accurately measure 1 ml each of the test solution and reference solution in a 100 mL volumetric flask and dilute to volume, mix well and use for the system suitability test.

## Chromatographic conditions

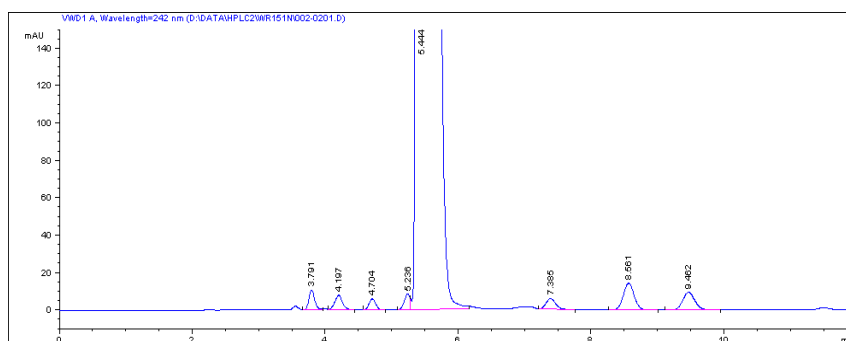
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:acetonitrile:triethylamine solution (dilute 7.5 mL of triethylamine with water to 1000 mL, adjust pH to 3.0±0.5 with phosphoric acid) =40:20:40
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 242 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2WR151N001-0101



The chromatogram of the test solution --- HPLC2WR151N002-0201

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dexamethasone Sodium Phosphate	5.65	253.7	10314	/	1.06
Dexamethasone	8.57	317.6	13316	11.2	1.06

# Dexamethasone Sodium Phosphate Eye Drops

Dexamethasone sodium phosphate (10016-0011) – Method number WR153

## 地塞米松磷酸钠滴眼液

### Assay

Test solution: Accurately measure a quantity of the substance and dilute with mobile phase to produce a solution of 50 µg/mL as the test solution.

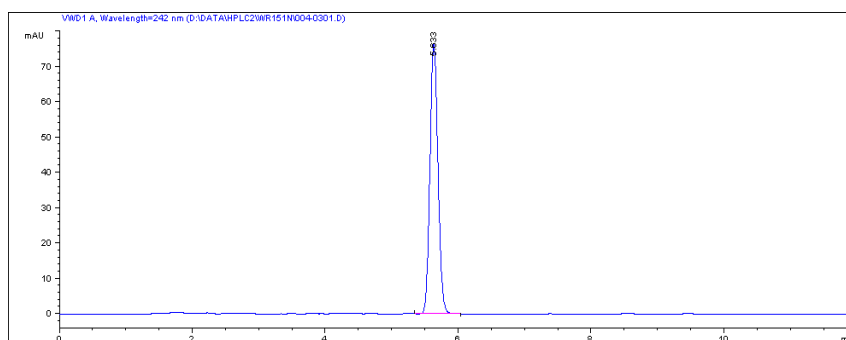
Reference solution: Dissolve an accurately weighed quantity of dexamethasone CRS in mobile phase to produce a solution of 50 µg/mL as the reference solution.

### Chromatographic conditions

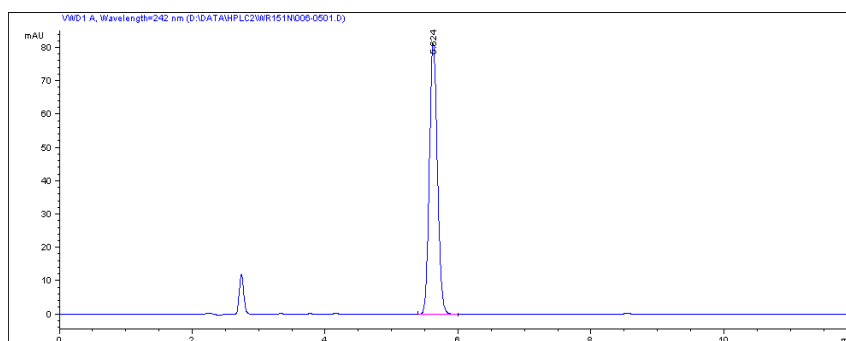
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm, (880975-902)
- Mobile phase: methanol : acetonitrile : triethylamine solution (dilute 7.5 mL of triethylamine with water to 1000 mL, adjust pH to 3.0±0.5 with phosphoric acid) = 40:20:40
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 242 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR151N004-0301



The chromatogram of the test solution--- HPLC2WR151N006-0501

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dexamethasone Sodium Phosphate	5.62	682.9	9955	/	1.07

# Dexamethasone Sodium Phosphate Injection

Dexamethasone sodium phosphate (10016-0011) – Method number WR152

## 地塞米松磷酸钠注射液

### Assay

Test solution: Accurately measure a quantity of the injection fluid and dilute with mobile phase to produce a solution of 50 µg/mL as the test solution.

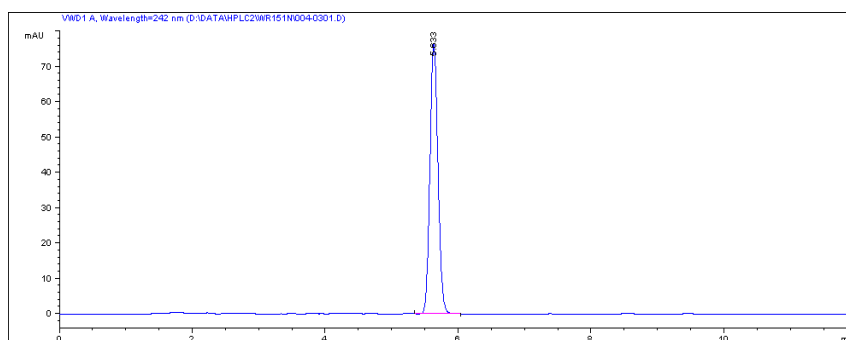
Reference solution: Dissolve an accurately weighed quantity of dexamethasone CRS in mobile phase to produce a solution of 50 µg/mL as the reference solution.

### Chromatographic conditions

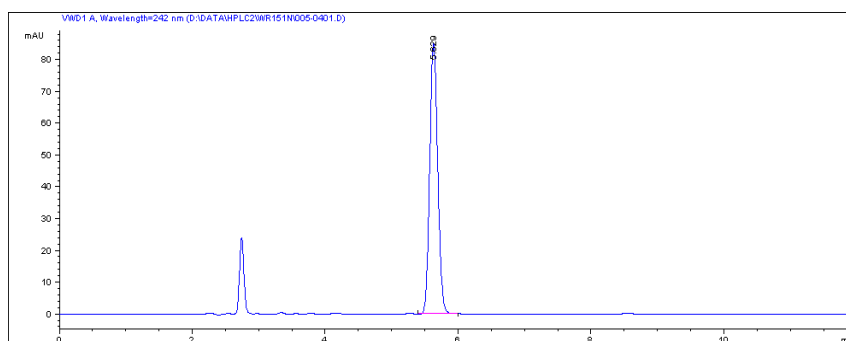
- Column : Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm, (880975-902)
- Mobile phase: methanol : acetonitrile : triethylamine solution (dilute 7.5 mL of triethylamine with water to 1000 mL, adjust pH to 3.0±0.5 with phosphoric acid) = 40:20:40
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 242 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR151N\004-0301



The chromatogram of the test solution --- HPLC2\WR151N\005-0401

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dexamethasone Sodium Phosphate	5.63	716.0	9506	/	1.07

# Diazepam – 地西洋

## Diazepam – Method number WR029

### Assay

Test solution: Dissolve an accurately weighed quantity of diazepam in methanol to produce a solution of 0.45 mg/mL as the test solution.

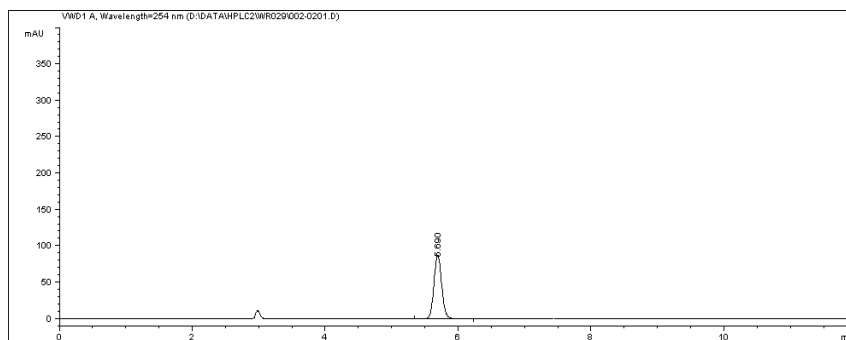
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask and dilute with methanol to volume, mix well and use as the reference solution.

### Chromatographic conditions

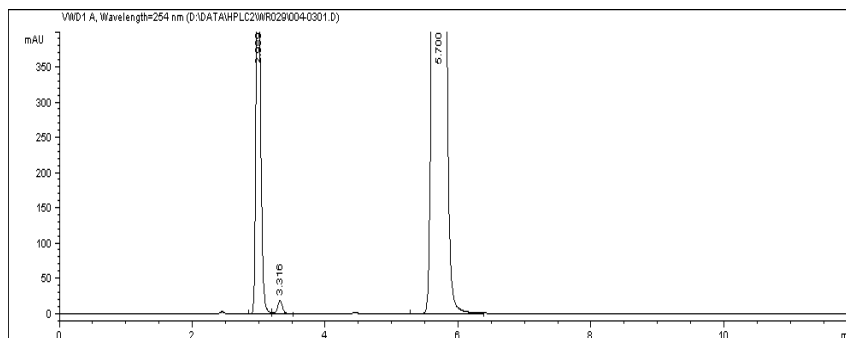
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol-water=80:20
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR029002-0201.D



The chromatogram of the test solution--- HPLC2WR029004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Diazepam	5.70	33660.1	9409	13.1	1.08
Impurity1	2.99	2699.6	9339	/	1.17
Impurity2	3.32	100.1	10905	2.6	0.90

# Scopolamine Butylbromide Injection – 丁溴东莨菪碱注射液

## Scopolamine butylbromide (0130-9501) – Method number WR001

### Assay

Test solution: Accurately measure a quantity of the injection fluid, dilute with mobile phase to produce a solution of 0.5 mg/mL, mix well and use as the test solution.

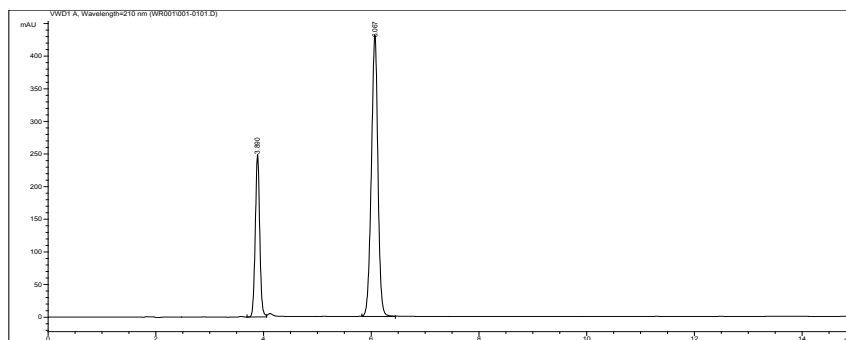
Reference solution: Dissolve an accurately weighed quantity of scopolamine butylbromide CRS in mobile phase to produce a solution of 0.5 mg/mL as the reference solution.

### Chromatographic conditions

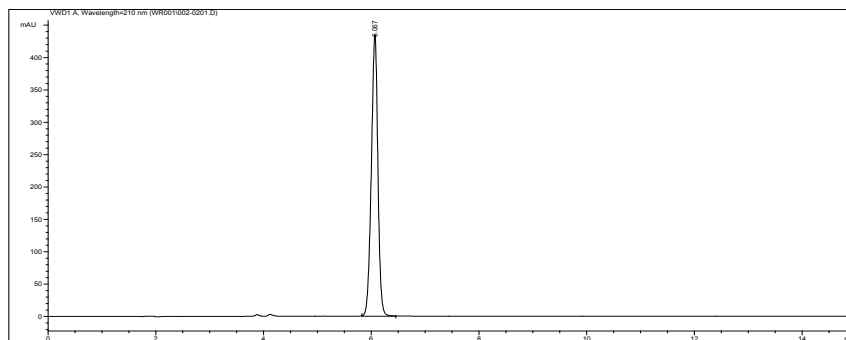
- Column : Agilent ZORBAX SB-Phenyl 4.6x250mm, 5 µm (880975-912)
- Mobile phase: 0.008 mol/L sodium laurylsulfate in a mixture of 0.004 % phosphoric acid solution : acetonitrile =40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability---HPLC1\WR001\001-0101



The chromatogram of the test solution--- HPLC1\WR001\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Scopolamine Hydrobromide	3.89	1423.9	11188	/	1.02
Scopolamine Butylbromide	6.07	3653.2	10780	12.0	0.97

# Paracetamol Drops – 对乙酰氨基酚滴剂

Paracetamol (100018-200107) Theophylline (100121-199903) – Method number WA016

## Assay

Internal standard solution: Dissolve a quantity of theophylline CRS in water to produce a solution of 1.0 mg/mL, mix well.

Test solution: Dissolve an accurately measured quantity of the substance in water to produce a solution of 0.6 mg/mL. Accurately measured 5 mL each of this solution and the internal standard solution in a 50 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

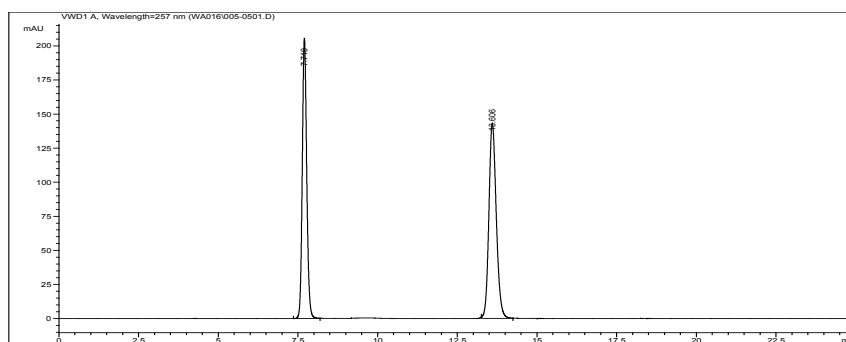
Reference solution: Repeat the procedure using paracetamol CRS dried to constant weight at 105 °C and use as the reference solution.

## Chromatographic conditions:

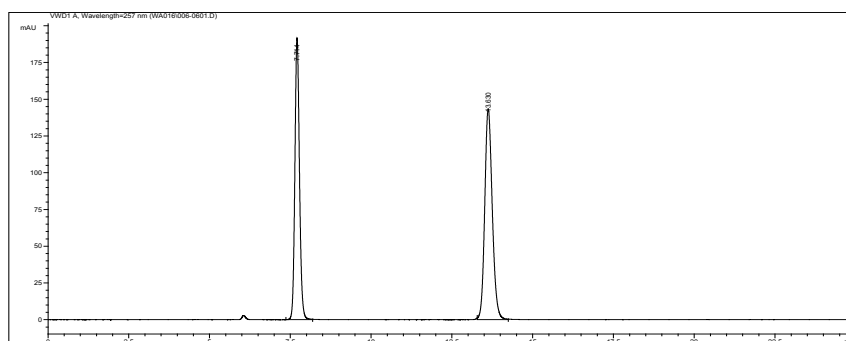
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : 0.05 mol/L ammonium acetate solution = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 257 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA016\005-0501



The chromatogram of the test solution --- HPLC2\WA016\006-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Paracetamol	7.71	1894.2	13050	/	1.08
Theophylline	13.63	2320.5	16475	17.0	1.12

# Paracetamol Drops – 对乙酰氨基酚滴剂

4-Aminophenol (ACROS) Paracetamol (100018-200107) – Method number WA016

## Assay

Test solution: Dissolve a quantity of the substance in water to produce a solution of 2 mg/mL, mix well and use as the test solution.

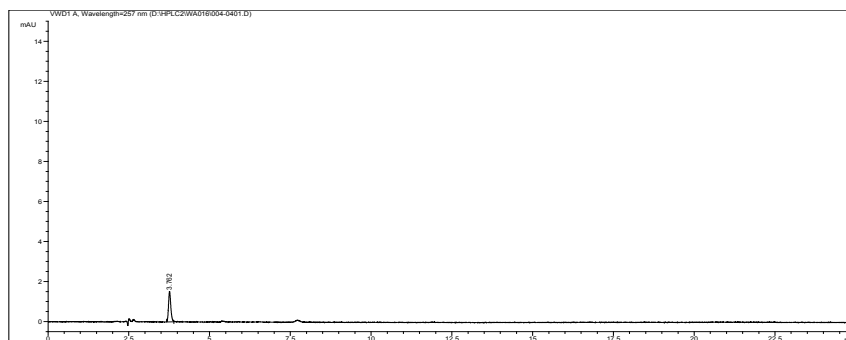
Reference solution: Prepare a solution of 2 µg of 4-aminophenol CRS per mL in water as the reference solution.

## Chromatographic conditions:

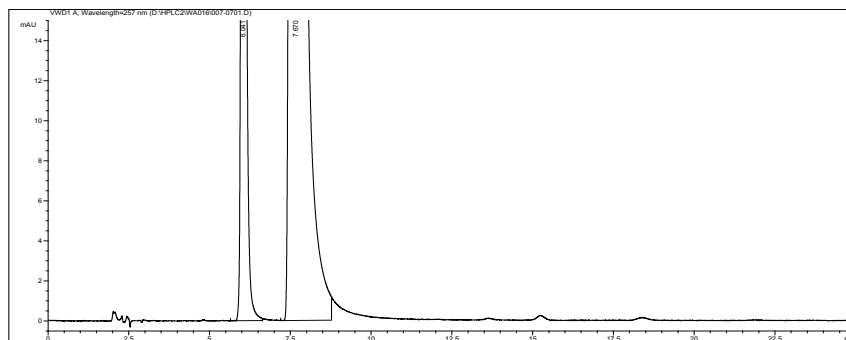
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : 0.05 mol/L ammonium acetate solution = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 257 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA016\004-0401



The chromatogram of the test solution --- HPLC2\WA016\007-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Paracetamol	7.66	48063.4	8009	/	1.21
4-Aminophenol	3.76	/	/	/	/



# Paracetamol Chewable Tablets – 对乙酰氨基酚咀嚼片

## 4-Aminophenol (ACROS) Paracetamol (100018-200107) – Method number WA250

### Assay

Test solution: To an accurately weighed quantity of the powder, equivalent to about 100 mg of paracetamol, add a quantity of mobile phase in a 10 mL volumetric flask, shake to dissolve the paracetamol, dilute with mobile phase to volume, mix well, filter and use the filtrate as the test solution.

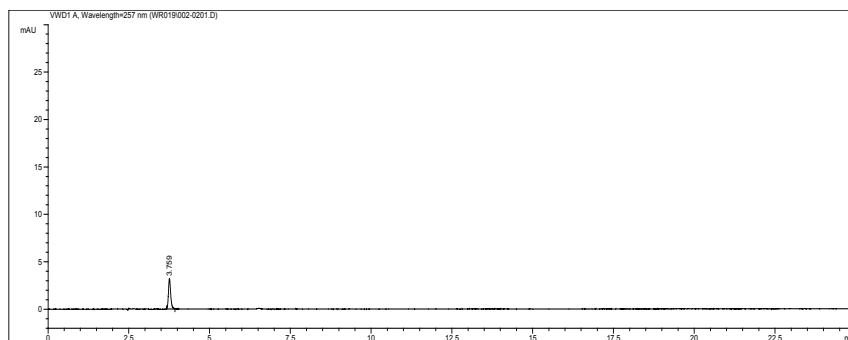
Reference solution: Dissolve a quantity of paracetamol CRS in mobile phase to produce a solution of 10 µg/mL as the reference solution.

### Chromatographic conditions

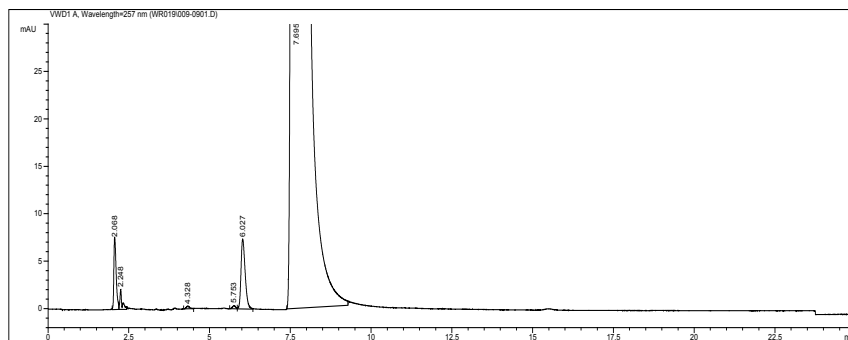
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : 0.05 mol/L ammonium acetate solution = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature: 30 °C
- Detector wavelength: 257 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR019\002-0201



The chromatogram of the test solution --- HPLC2\WR019\009-0901

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
4-aminophenol	3.76	/	/	/	/
Paracetamol	7.73	63847.9	4957	5.0	1.25

# Paracetamol Granules – 对乙酰氨基酚颗粒

4-Aminophenol (ACROS) Paracetamol (100018-200107)– Method number WA017

## Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 100 mg of paracetamol, in a 10 mL volumetric flask, add a quantity of mobile phase and shake to dissolve the paracetamol, dilute with mobile phase to volume and shake well. Filter and use the filtrate as the test solution.

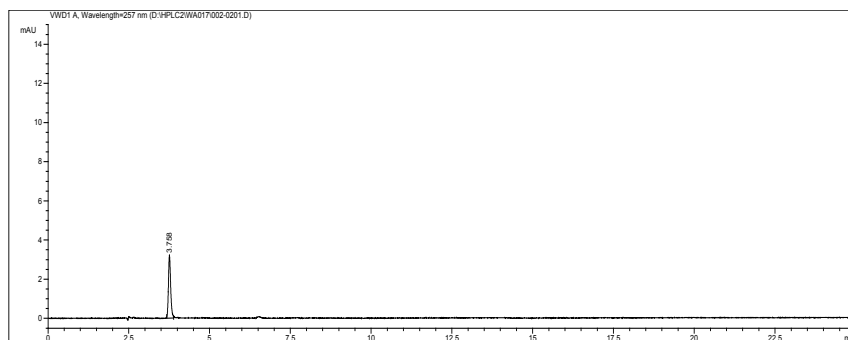
Reference solution: Prepare a solution of 10 µg of 4-aminophenol CRS per mL in mobile phase as the reference solution.

## Chromatographic conditions:

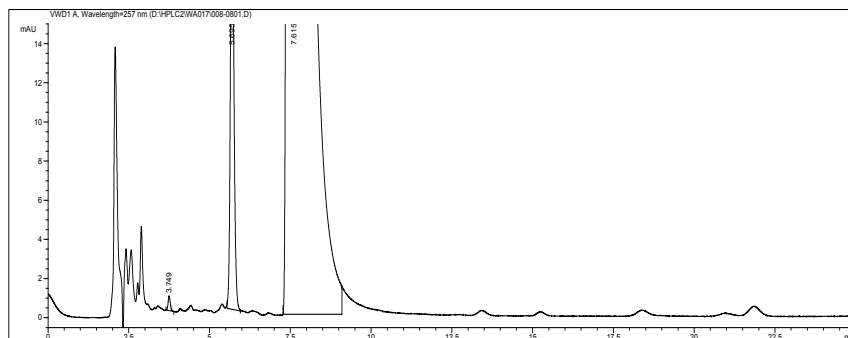
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : 0.05 mol/L ammonium acetate solution = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 257 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA017\002-0101



The chromatogram of the test solution --- HPLC2\WA017\008-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
4-Aminophenol	3.75	3.5	15720	/	0.95
Paracetamol	7.62	73270.6	3757	5.67	1.29
Impurity	5.70	178.8	16125	13.0	1.15

# Paracetamol Effervescent Tablets – 对乙酰氨基酚泡腾片

Paracetamol (100018-200107) – Method number WA015

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 25 mg of paracetamol, in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well. Filter and accurately transfer 10 mL of the filtrate to a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

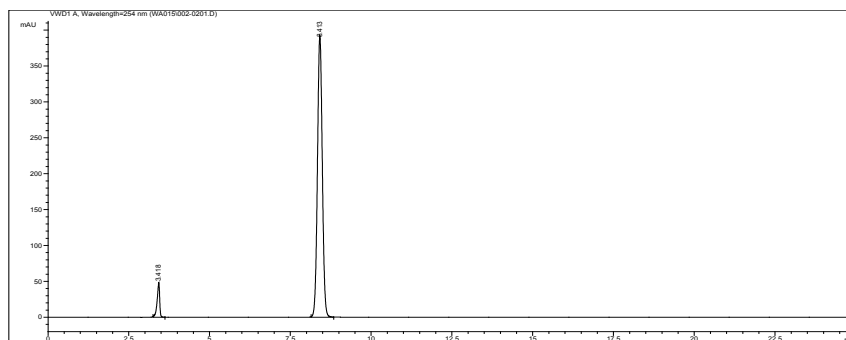
Reference solution: Repeat the procedure using paracetamol CRS and use as the reference solution.

## Chromatographic conditions

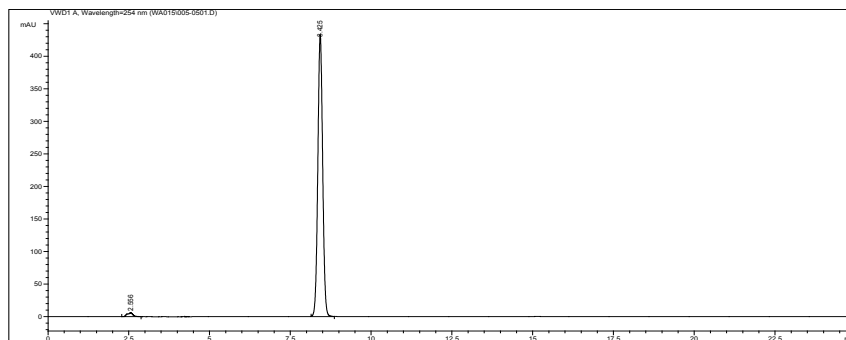
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: phosphate BS (pH 4.5) (dissolve 15.04 g sodium dihydrogen phosphate and 0.0627 g disodium hydrogen phosphate in 1000 mL of water, adjust pH to 4.5) : methanol = 80:20
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 254 nm
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the system suitability ---HPLC2WA015002-0201



The chromatogram of the test solution --- HPLC2WA015005-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
4-Aminophenol	3.43	264.0	10788	/	0.74
Paracetamol	8.41	4097.8	14398	24.1	1.03

# Paracetamol Effervescent Tablets – 对乙酰氨基酚泡腾片

## 4-Aminophenol (ARCOS) – Method number WA015

### Assay

Test solution: Accurately weigh a quantity of powder, equivalent to about 25 mg of paracetamol, in a 50 mL volumetric flask, add a quantity of mobile phase and shake to dissolve the paracetamol, dilute with mobile phase to volume and mix well. Filter and use the filtrate as the test solution.

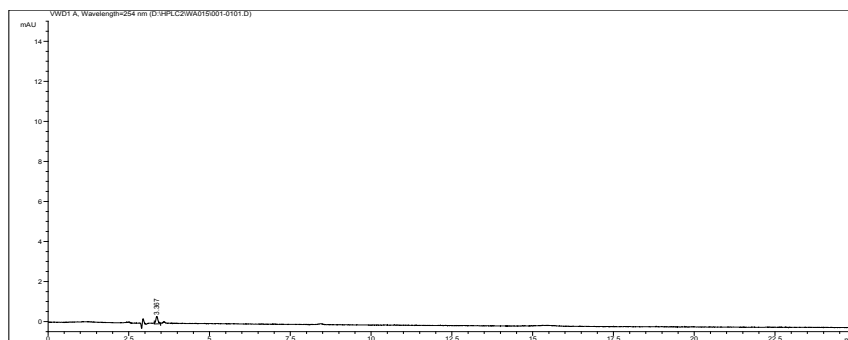
Reference solution: Prepare a solution of 0.5 µg of 4-aminophenol CRS per mL with mobile phase as the reference solution.

### Chromatographic conditions

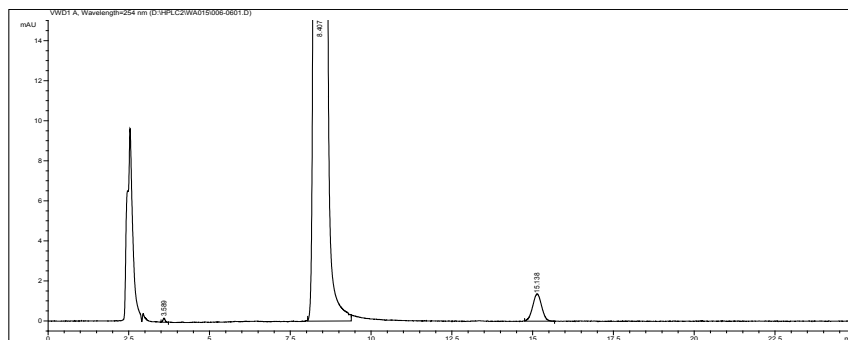
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: phosphate BS (pH 4.5) (dissolve 15.04 g sodium dihydrogen phosphate and 0.0627 g disodium hydrogen phosphate in 1000 mL of water, adjust pH to 4.5) : methanol = 80:20
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 254 nm
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA015\001-0101



The chromatogram of the test solution --- HPLC2\WA015\006-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
4-Aminophenol	3.59	0.9	14087	/	1.03
Paracetamol	8.41	20645.1	13191	23.3	1.08

# Famciclovir – 泛昔洛韦

Famciclovir (100628-200301) – Method number WA076

## Assay

Test solution: Prepare a solution of 0.1 mg/mL in mobile phase.

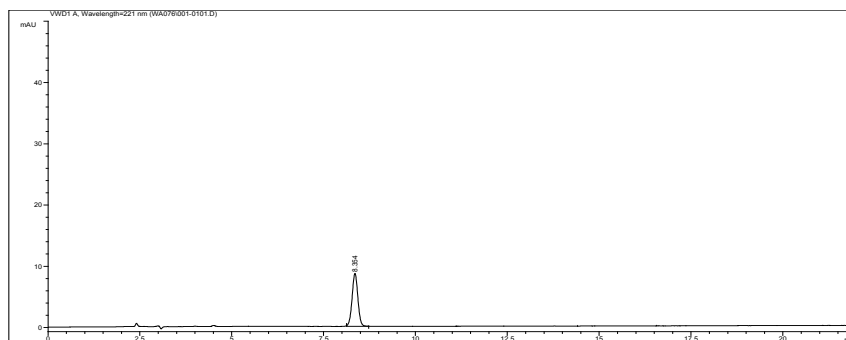
Reference solution: Prepare a solution of 1.0 µg/mL with mobile phase.

## Chromatographic conditions

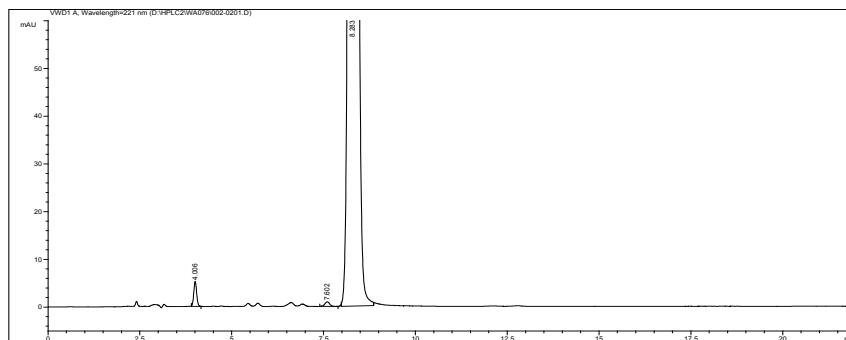
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (990975-914)
- Mobile phase: acetonitrile : 0.02 mol/L potassium dihydrogen phosphate = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 221 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA0076\001-0101



The chromatogram of the test solution --- HPLC2\WA076\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>i</sub>
Famciclovir	8.28	9086.1	12926	2.6	1.19
Impurity1	4.01	28.6	12759	/	1.07
Impurity2	7.60	8.6	16541	19.0	0.99

# Famciclovir Capsules – 泛昔洛韦胶囊

Famciclovir (100628-200301) – Method number WA078

## Assay

Test solution: Dissolve an accurately weighed quantity of the mixed contents in mobile phase to produce a solution of about 50 mg/mL, shake well, filter and use the filtrate as the test solution.

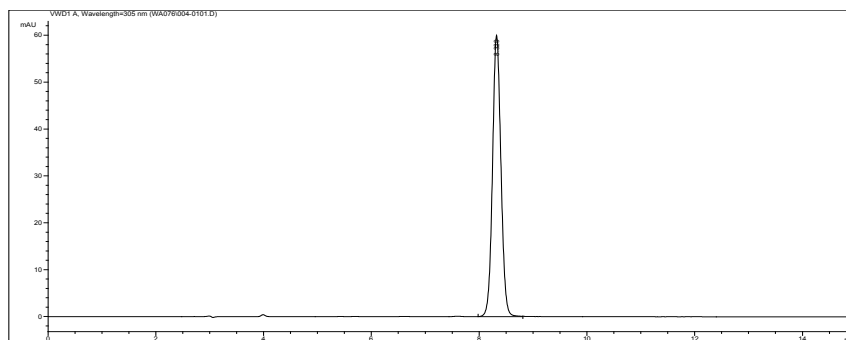
Reference solution: Repeat the procedure using famciclovir CRS to produce the reference solution.

## Chromatographic conditions

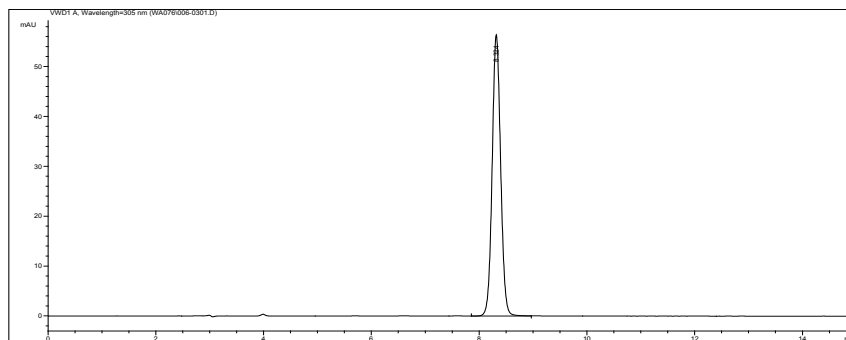
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (990975-914)
- Mobile phase: acetonitrile : 0.02 mol/L potassium dihydrogen phosphate = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 305 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA0076\004-0101



The chromatogram of the test solution--- HPLC2\ WA076\006-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Famciclovir	8.32	614.5	13553	/	1.03

# Famciclovir Tablets – 泛昔洛韦片

Famciclovir (100628-200301) – Method number WA077

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase to produce a solution of about 50 mg/mL, mix well, filter and use the filtrate as the test solution.

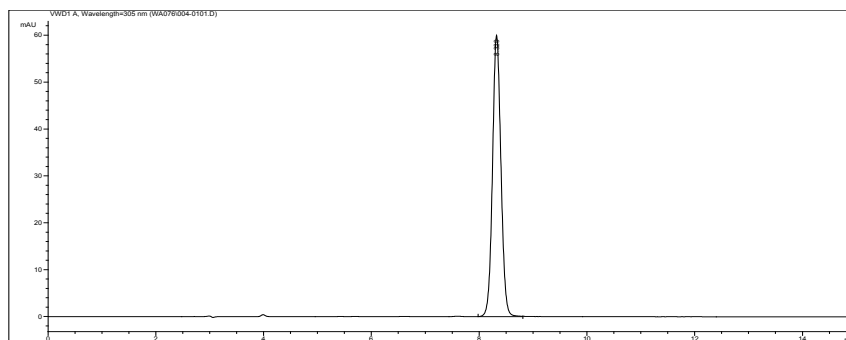
Reference solution: Repeat the procedure using famciclovir CRS to produce the reference solution.

## Chromatographic conditions

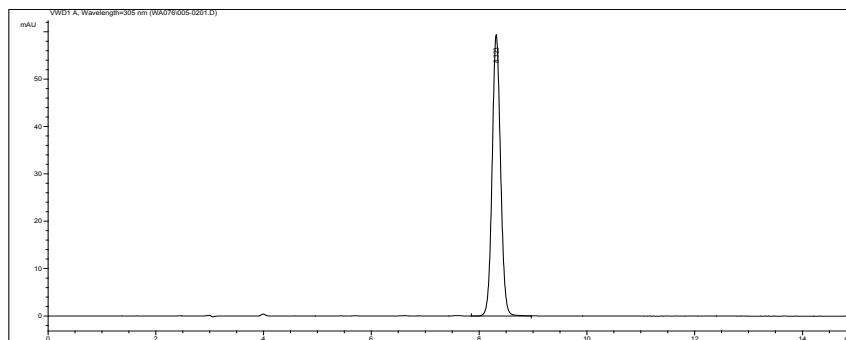
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (990975-914)
- Mobile phase: acetonitrile : 0.02 mol/L potassium dihydrogen phosphate = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 305 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA0076\004-0101



The chromatogram of the test solution --- HPLC2\ WA076\005-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Famciclovir	8.32	642.7	13814	/	1.04

# Felodipine – 非洛地平

## Felodipine – Method number WA110

### Assay

Test solution: Prepare a solution of 1 mg/mL in mobile phase.

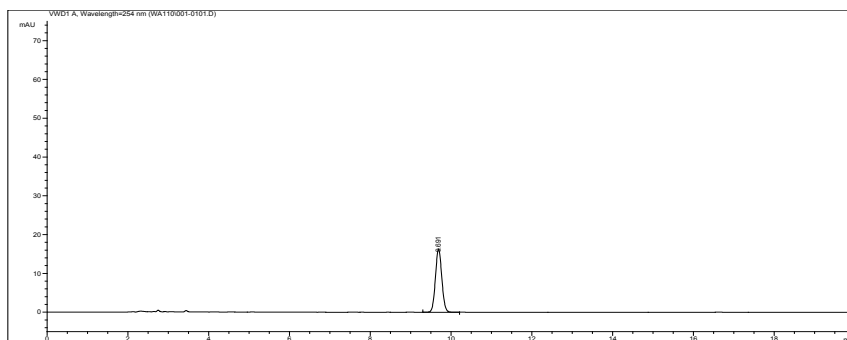
Reference solution: Prepare a solution of 15 µg/mL with mobile phase.

### Chromatographic conditions

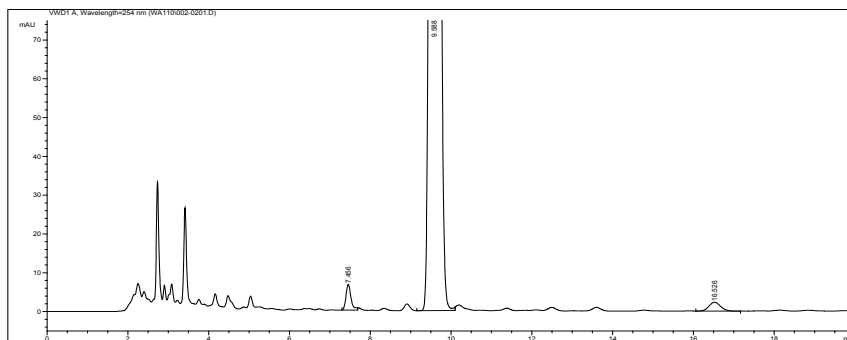
- Column: Agilent ZORBAX S B-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile : methanol : phosphate BS (mix 8.0 mL of 5.5 % phosphoric acid solution and 50.0 mL of 15.6 % sodium dihydrogen phosphate solution, dilute to 1000 mL with water, mix well) = 45:25:30
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA110\001-0101



The chromatogram of the test solution--- HPLC1\ WA110\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Felodipine	9.59	11875.6	15805	8.3	1.07
Impurity1	7.46	55.3	19847	/	1.38
Impurity2	16.52	44.9	15926	16.7	1.08



# Felodipine Tablets – 非洛地平片

## Felodipine – Method number WA111

### Assay

Test solution: Dissolve a quantity of the powdered tablets in mobile phase to produce a solution containing 1 mg/mL, treat ultrasonically to dissolve the felodipine, filter and use the filtrate as the test solution.

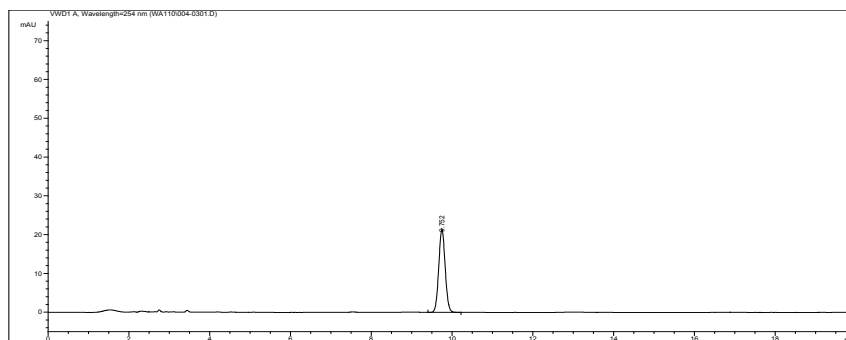
Reference solution: Accurately measure a quantity of the test solution, dilute with mobile phase to produce the solution containing 20 µg/mL as the reference solution.

### Chromatographic conditions

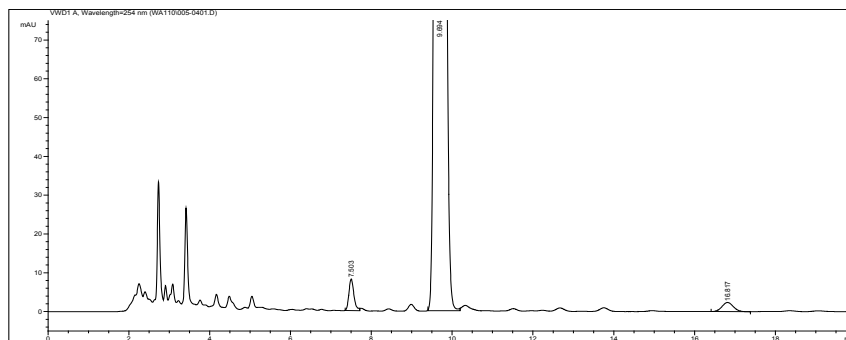
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm, (880975-902)
- Mobile phase: acetonitrile : ethanol : phosphate BS (mix 8.0 mL of 5.5 % phosphoric acid solution and 50.0 mL of 15.6 % sodium dihydrogen phosphate solution, dilute to 1000 mL with water, mix well) = 45:25:30
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA110\004-0301



The chromatogram of the test solution--- HPLC1\ WA110\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>i</sub>
Felodipine	9.69	11922.6	16346	8.4	1.08
Impurity1	7.50	69.6	19092	/	1.39
Impurity2	16.82	45.3	17304	17.4	1.04

# Paracetamol and Caffeine Tablets – 酚咖片

Paracetamol (100018-200107) Caffeine,

Benzoic acid (100419-200301) – Method number WA312

## Assay

Internal standard solution: dissolve a quantity of benzoic acid with methanol to produce a solution of 3.5 mg/mL, mix well.

Reference solution: To an accurately weighed quantity of paracetamol CRS and caffeine CRS dried to constant weight at 105 °C, add a mixture of methanol-glacial acetic acid (95:5) in a volumetric flask to produce a solution of 0.25 mg of paracetamol and 0.03 mg of caffeine per mL. Accurately measure 20 mL of the resulting solution and 5 mL of internal standard solution in a 50 mL volumetric flask, dilute with a mixture of methanol-glacial acetic acid (95:5) to volume, mix well and use as the reference solution.

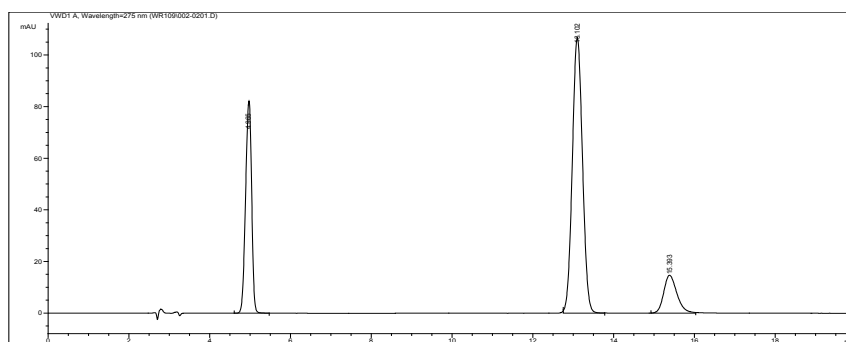
Test solution: Accurately weigh 40 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.25 g of paracetamol, in a 100 mL volumetric flask, add about 75 mL of a mixture of methanol-glacial acetic acid (95:5), shake for 30 minutes, dilute with the mixture to volume, mix well and filter. Accurately measure 2 mL of the filtrate and 5 mL of internal standard solution in a 50 mL volumetric flask, dilute with the mixture of methanol-glacial acetic acid (95:5) to volume, mix well and use as the test solution.

## Chromatographic conditions

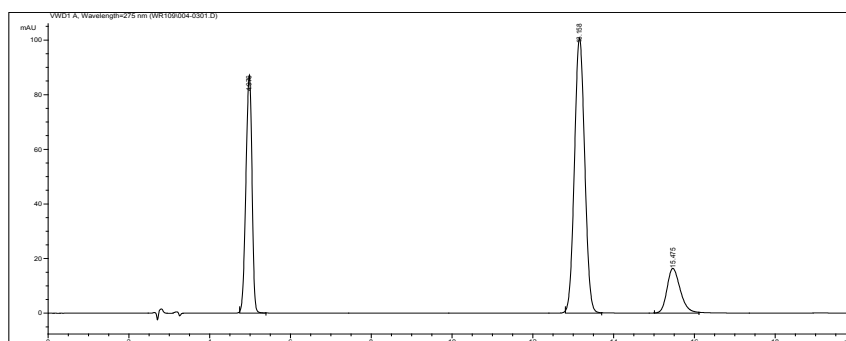
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol : water : glacial acetic acid = 28:69:3
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 275 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2WR109002-0201



The chromatogram of the test solution --- HPLC2WR109004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Paracetamol	4.98	908.8	4664		0.96
Benzoic acid	13.16	1775.1	12533	21.5	1.03
caffeine	15.47	372.2	11018	4.4	1.18

# Fluconazole Tablets – 氟康唑片

## Fluconazole (100314-0101) – Method number WA277

### Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. To an accurately weighed quantity, equivalent to about 50 mg of fluconazole, add a quantity of mobile phase in a 100 mL volumetric flask, treat ultrasonically to dissolve the fluconazole, dilute to volume, mix well, filter and use the filtrate as the test solution.

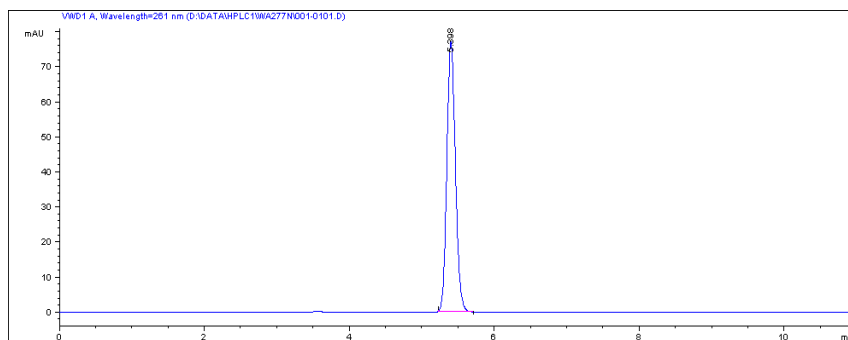
Reference solution: Dissolve an accurately weighed quantity of fluconazole CRS with mobile phase to produce a solution of 0.5 mg/mL as the reference solution.

### Chromatographic conditions

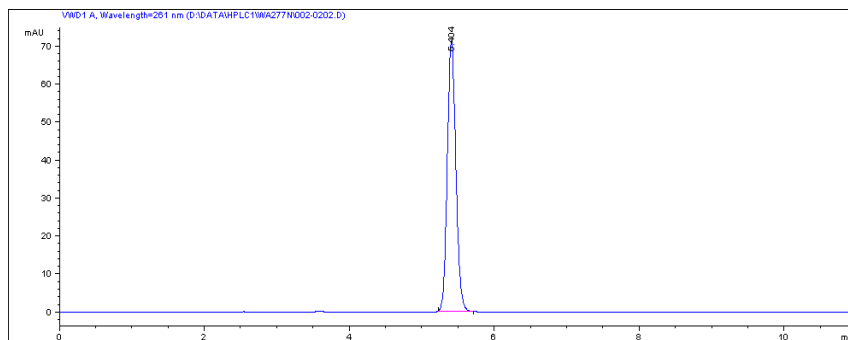
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 7.0 with sodium hydroxide) : methanol = 55:45
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 261 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA277N001-0101



The chromatogram of the test solution --- HPLC1\WA277N002-0202

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Fluconazole	5.41	590.8	9094	/	1.09

# Fluconazole and Sodium Chloride Injection – 氟康唑氯化钠注射液

## Fluconazole (100314-0101) – Method number WA334

### Assay

Test solution: Accurately measure a quantity of the substance and dilute with mobile phase to produce a solution of about 0.5 mg/mL as the test solution.

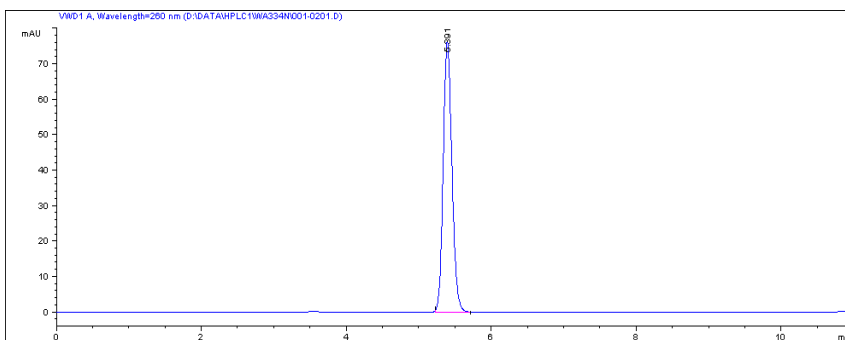
Reference solution: Dissolve an accurately weighed quantity of fluconazole CRS in mobile phase to produce a reference solution of 0.5 mg/mL.

### Chromatographic conditions

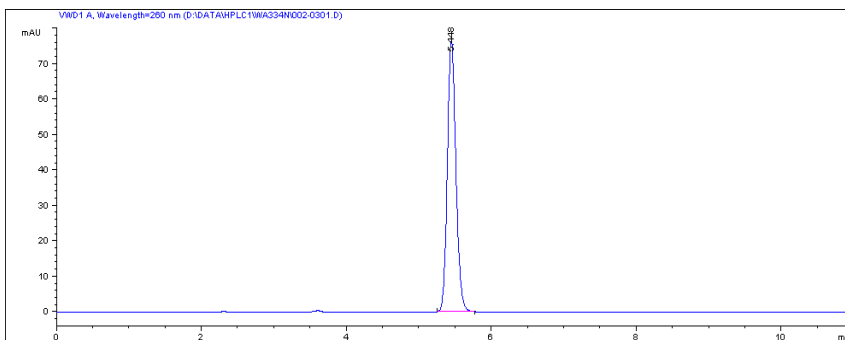
- Column: Agilent ZORBAX XDB C18 4.6X250 mm, 5 µm (990967-906)
- Mobile phase: methanol : phosphate BS (dissolve 6.8 g of potassium dihydrogen phosphate in a quantity of water, adjust pH to 7.0 with 0.1 mol/L sodium hydroxide solution, dilute to 1000 mL) = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 10µL
- Column temperature: 30 °C
- Detector wavelength: 260 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA334\N001-0201



The chromatogram of the test solution ---HPLC1\WA334\N002-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Fluconazole	5.45	632.9	8514	/	1.08

# Fleroxacin – 氟罗沙星

Fleroxacin (130458-200301) – Method number WA127

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase to produce the test solution containing 2.0 mg/mL.

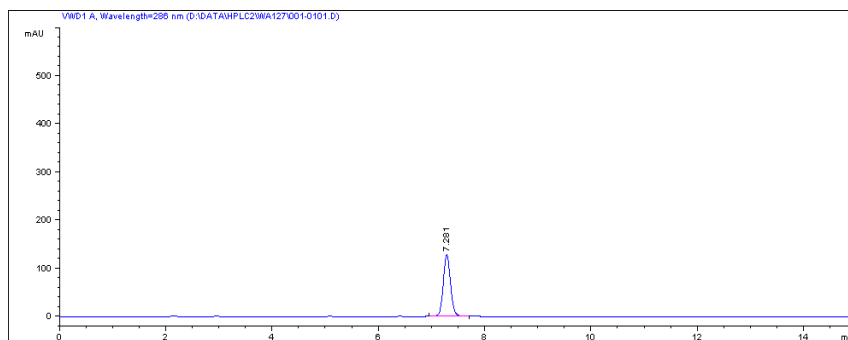
Reference solution: Dissolve an accurately measured quantity of test solution in mobile phase to produce a reference solution of 20 µg/mL.

## Chromatographic conditions

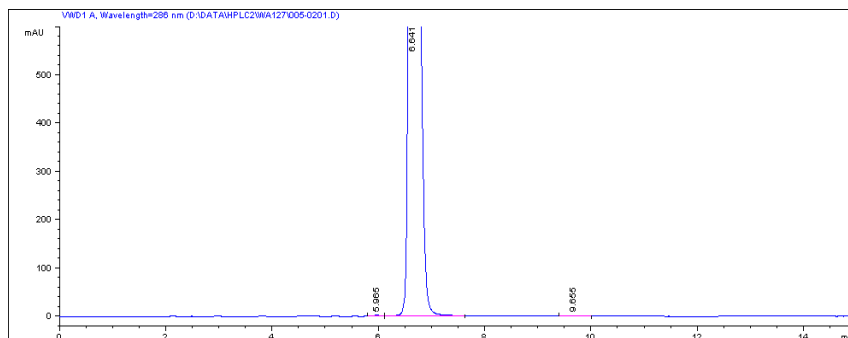
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm, (880975-902)
- Mobile phase: triethylamine phosphate solution (add 5 mL of triethylamine and 7 mL of phosphoric acid to water, and dilute to volume of 1000 mL) : acetonitrile = 85:15
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 286 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA127\001-0101



The chromatogram of the test solution--- HPLC2\ WA127\005-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Fleroxacin	6.63	30385.8	6452	2.5	1.67
Impurity1	5.96	16.6	15812	/	/
Impurity2	9.66	12.7	17561	9.7	0.98

# Fleroxacin Capsules – 氟罗沙星胶囊

Fleroxacin (130458-200301) – Method number WA129

## Assay

**Test solution:** Transfer an accurately weighed quantity of the mixed contents of the capsules, equivalent to about 100 mg of fleroxacin, to a 100 mL volumetric flask, add a quantity of mobile phase to dissolve, dilute to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

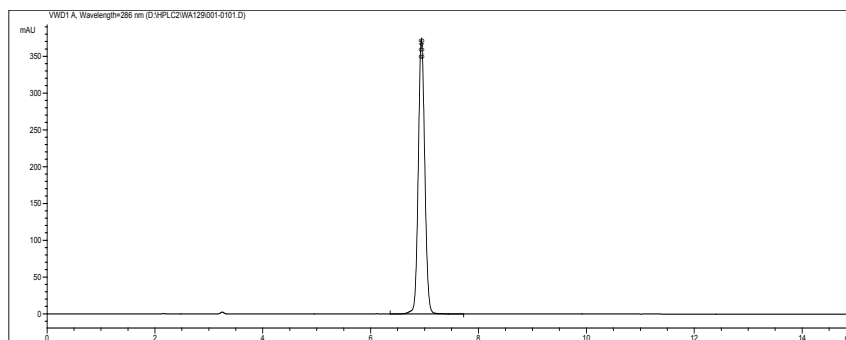
**Reference solution:** Accurately weigh about 50 mg of fleroxacin CRS in a 50 mL volumetric flask and dissolve in mobile phase, dilute to volume. Measure accurately 5 mL of the solution in a 100 mL volumetric flask, dilute to volume and use as the reference solution.

## Chromatographic conditions

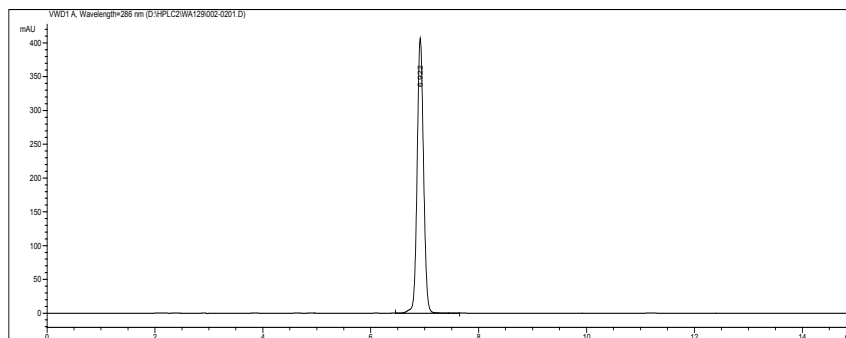
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm, (880975-902)
- Mobile phase: triethylamine phosphate solution (add 5 mL of triethylamine and 7 mL of phosphoric acid to water, and dilute to volume of 1000 mL) : acetonitrile = 85:15
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 286 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA129\001-0101



The chromatogram of the test solution--- HPLC2\ WA129\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Fleroxacin	6.92	3349.6	13404	/	1.02

# Fleroxacin Tablets – 氟罗沙星片

Fleroxacin (130458-200301) – Method number WA128

## Assay

Test solution: Accurately weigh 10 tablets and grind to a powder. Dissolve an accurately weighed quantity of powder, equivalent to about 100 mg of fleroxacin, in mobile phase and dilute to 100 mL, mix well and filter. Accurately measure 5 mL of the filtrate in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

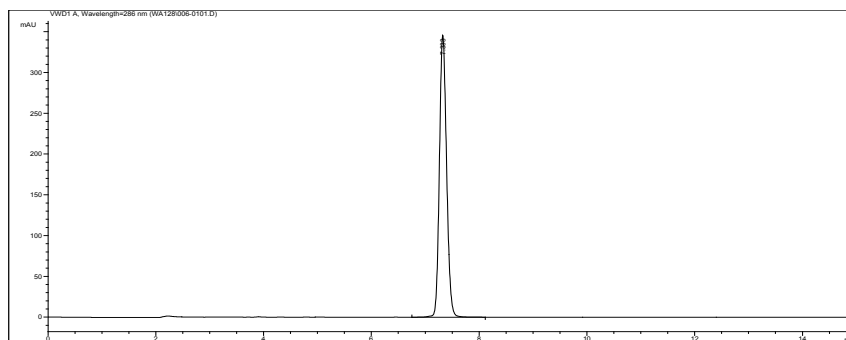
Reference solution: accurately weigh about 50 mg of fleroxacin CRS in a 50ml volumetric flask and dissolve in the mobile phase, dilute to volume. Measure accurately 5 mL of the solution in a 100 mL volumetric flask, dilute to volume and use as the reference solution.

## Chromatographic conditions

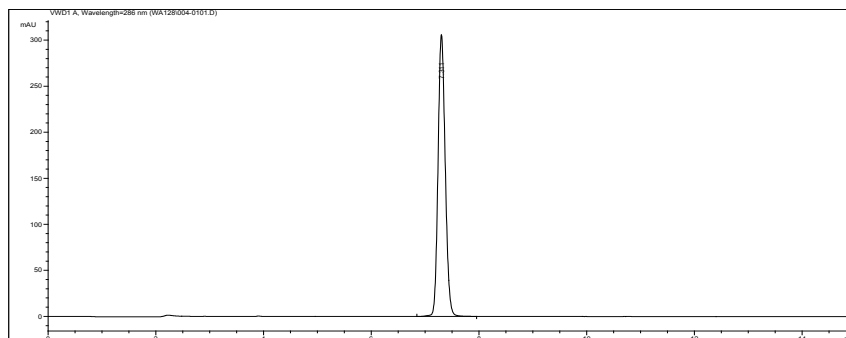
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: triethylamine phosphate solution (add 5 mL of triethylamine and 7 mL of phosphoric acid to water, and dilute to volume of 1000 mL) : acetonitrile = 85:15
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature : 30 °C
- Detector wavelength: 286 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA128\006-0101



The chromatogram of the test solution--- HPLC1\ WA128\004-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Fleroxacin	7.31	2835.0	12023	/	1.07

# Coenzyme Q<sub>10</sub> Capsules – 辅酶Q10胶丸

## Coenzyme Q<sub>10</sub> (140611-200102) – Method number WA196

### Assay

Test solution: Protect from light throughout the procedure. Split open 10 pills carefully. Add a quantity of dehydrated ethanol to the well-mixed contents, heat in a 50 °C water bath to dissolve the coenzyme Q<sub>10</sub>, allow to cool. Dilute with dehydrated ethanol to produce a solution containing 0.2 mg of coenzyme Q10 per mL, mix well and use as the test solution.

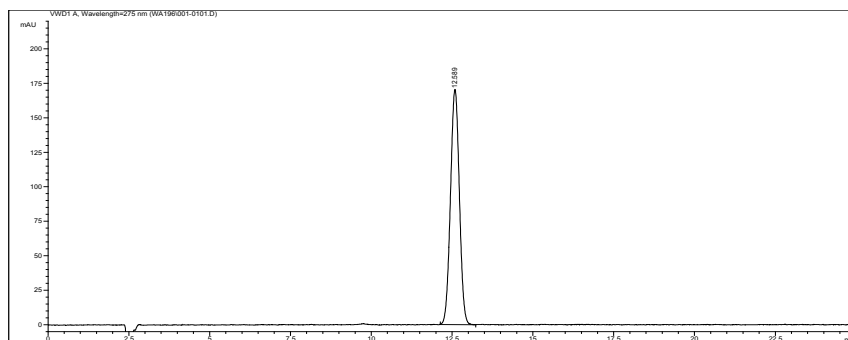
Reference solution: Dilute a quantity of coenzyme Q<sub>10</sub> CRS with dehydrate ethanol to produce a solution of 0.2 mg/mL, mix well and use as the reference solution.

### Chromatographic conditions

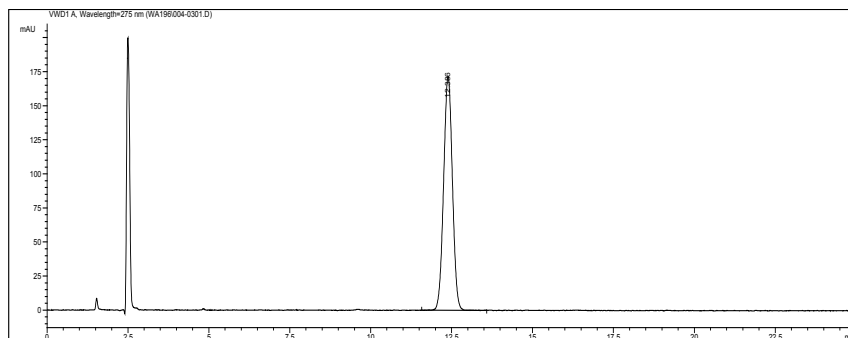
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: ethanol : methanol = 2:1
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature : 35 °C
- Detector wavelength: 275 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1WA196001-0101



The chromatogram of the test solution--- HPLC1WA196004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Coenzyme Q10	12.39	3233.1	10030	/	1.01



# Coenzyme Q<sub>10</sub> Capsules – 辅酶Q10胶丸

## Coenzyme Q<sub>10</sub> (140611-200102) – Method number WA196

### Assay

Test solution: Protect from light throughout the procedure. Split open 10 pills carefully. Add a quantity of dehydrated ethanol to the well-mixed contents, heat in a 50 °C water bath to dissolve the coenzyme Q<sub>10</sub>, allow to cool. Dilute with dehydrated ethanol to produce a solution containing 0.2 mg of coenzyme Q<sub>10</sub> per mL, mix well and use as the test solution.

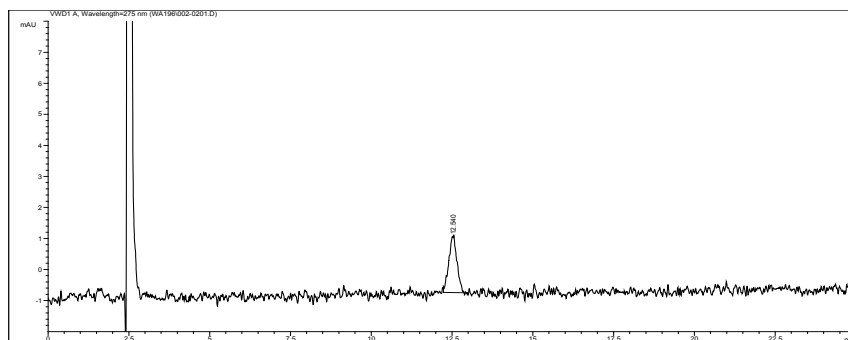
Reference solution: Accurately measure 1.0 mL of the test solution in a 100 mL volumetric flask, dilute with dehydrate ethanol to volume and use as the reference solution.

### Chromatographic conditions

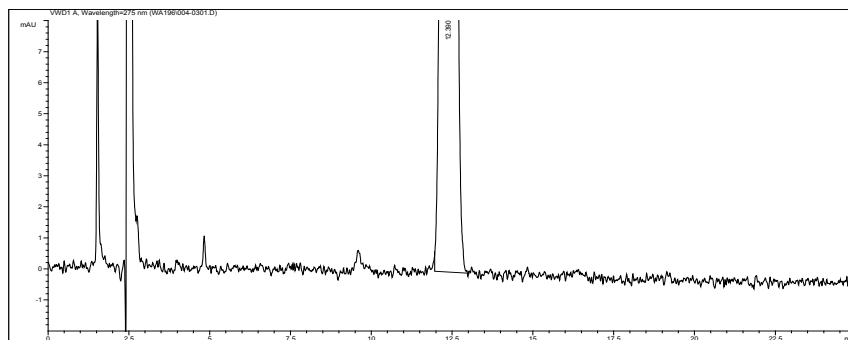
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: ethanol : methanol = 2:1
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature : 35 °C
- Detector wavelength: 275 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA196\002-0201



The chromatogram of the test solution--- HPLC1\WA196\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Coenzyme Q10	12.39	3233.1	10030	/	1.01

# Compound Diphenoxylate Tablets - Diphenoxylate

Diphenoxylate (ARCOS) – Method number WA116

复方地芬诺酯片-地芬诺酯-地芬诺酯

## Assay

Test solution: Accurately weigh 50 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powdered tablets, equivalent to about 2.5 mg of diphenoxylate hydrochloride, in a quantity of the mobile phase in 50 mL volumetric flask, shake well. Dilute with the mobile phase to volume, mix well, filter and use the filtrate as the test solution.

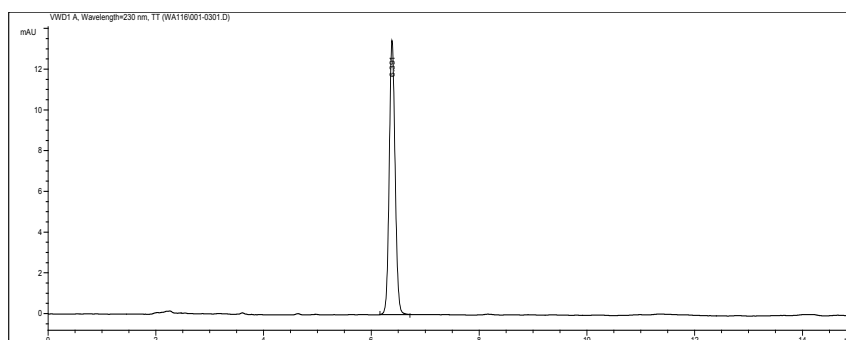
Reference solution: Dilute an accurately weighed quantity of diphenoxylate hydrochloride CRS dried to constant weight at 105 °C with mobile phase to produce a reference solution of 50 µg/mL.

## Chromatographic conditions

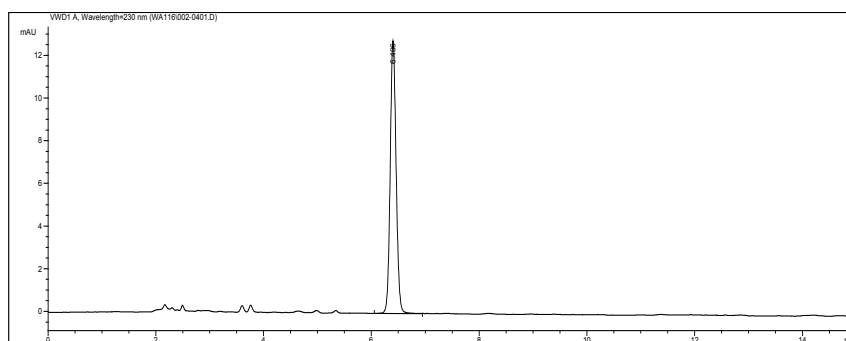
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: triethylamine phosphoric acid solution (add 4 ml of triethylamine add 500 mL of water and 1.8 ml of phosphoric acid, dilute to 1000 mL with water, mix well) : acetonitrile = 50:50, adjust the pH value to 3.10±0.2
- Flow rate : 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA116001-0301



The chromatogram of the test solution --- HPLC1\ WA116002-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Diphenoxylate	6.41	97.1	14650	/	1.05

# Compound Diphenoxylate Tablets – Atropine

Atropine (ARCOS) – Method number WA11

复方地芬诺酯片-阿托品

## Assay

Test solution: Dissolve an accurately weighed quantity of the powdered tablets, equivalent to about 50 mg of atropine sulfate, in a quantity of mobile phase in 50 mL volumetric flask, shake well. Dilute with mobile phase to volume, mix well, filter and use the filtrate as the test solution.

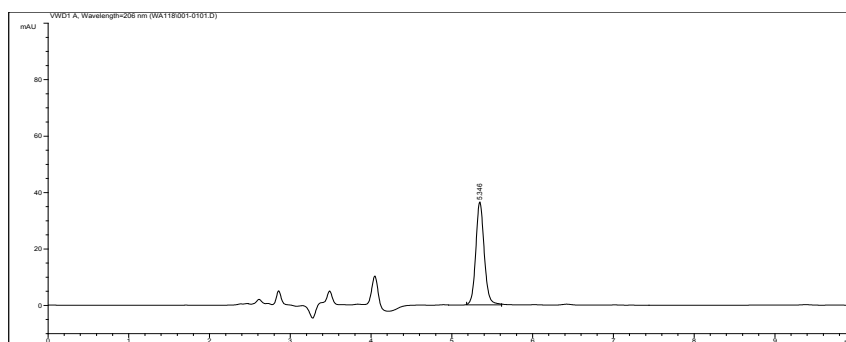
Reference solution: Dilute an accurately weighed quantity of atropine sulfate CRS dried to constant weight at 120 °C with mobile phase to produce a reference solution of 10 µg/mL.

## Chromatographic conditions

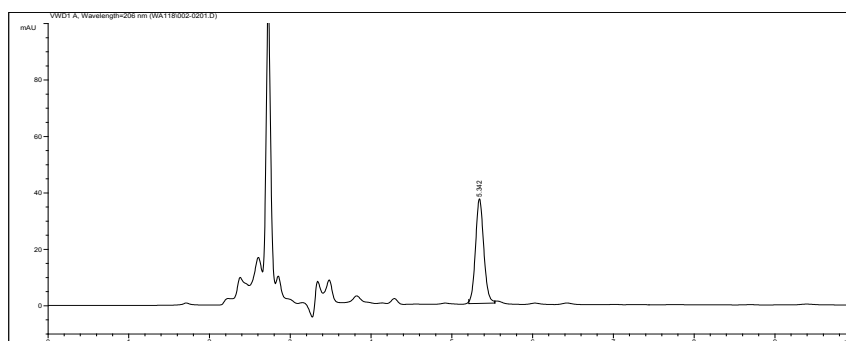
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: triethylamine phosphoric acid solution (add 4 mL of triethylamine add 500 mL of water and 1.8 mL of phosphoric acid, dilute to 1000 mL with water, mix well) : acetonitrile = 85:15, adjust the pH value to 5.8±0.2
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 206 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA118001-0101



The chromatogram of the test solution--- HPLC2\ WA118002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Atropine sulfate	5.34	266.6	13557	/	1.10

# Compound Dexamethasone Acetate Cream – 复方地塞米松乳膏

## Dexamethasone (100122-200304) – Method number WA118

### Assay

Internal standard solution: dissolve a quantity of methyltestosterone CRS in methanol to produce a solution of 0.20 mg/mL.

Reference solution: Accurately weigh about 13 mg of dexamethasone acetate CRS in a 50 mL volumetric flask, dissolve and dilute with methanol to volume, mix well. Accurately measure 5 ml each of this solution and the internal standard solution in a 50 mL volumetric flask, dilute with methanol to volume, mix well and use as the reference solution.

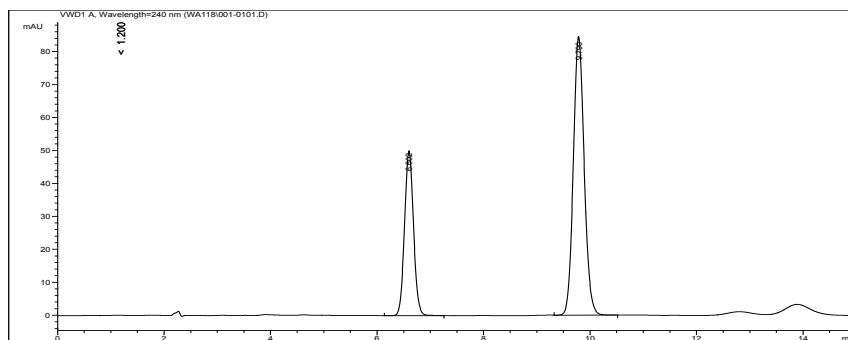
Test solution: Accurately weigh about 1.8 g of the substance in a 50 mL volumetric flask, add a quantity of methanol. Heat in a water bath at 80 °C until dissolved, allow to cool to room temperature. Accurately add 5 mL of the internal standard solution and dilute with methanol to volume. Mix well and keep in ice bath for 2 hours, filter immediately and use the filtrate as the test solution.

### Chromatographic conditions

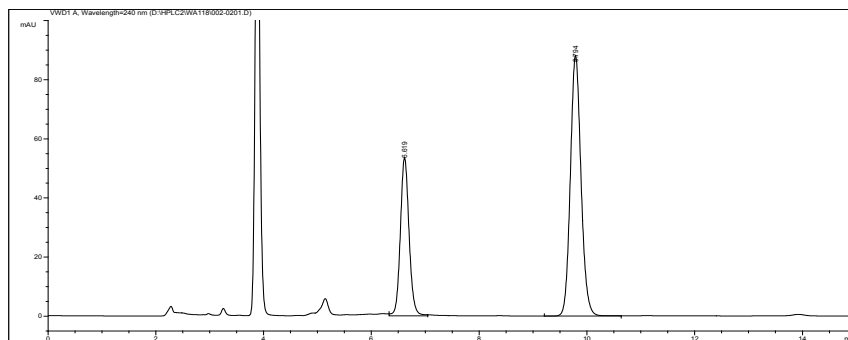
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:water = 70:30
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA118\001-0101



The chromatogram of the test solution --- HPLC2\WA118\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dexamethasone	6.62	601.8	8657	/	1.07
Methyltestosterone	9.79	1212.4	11652	9.8	1.09

# Compound Glycyrrhiza Oral Solution – 复方甘草口服溶液

## Morphine – Method number WA282

### Assay

Test solution: Using a column packed with octadecylsilane bonded silica gel, wash the column with 15 mL of a mixture of methanol-water (3:1) followed by 5 mL of water, then wash the column with an ammonia solution of about pH 9 until the eluent has about pH 9. Treat a quantity ultrasonically for 10 minutes and mix well. Accurately apply 0.5 mL to the washed column, add drop-wise a quantity ammonia TS to adjust the solution in the column to about pH 9, mix well, rinse with 20 mL of water when no more solvent elutes. Elute with 5 % acetic acid solution, collect the eluent in a 5 mL volumetric flask to volume, mix well and use as the test solution.

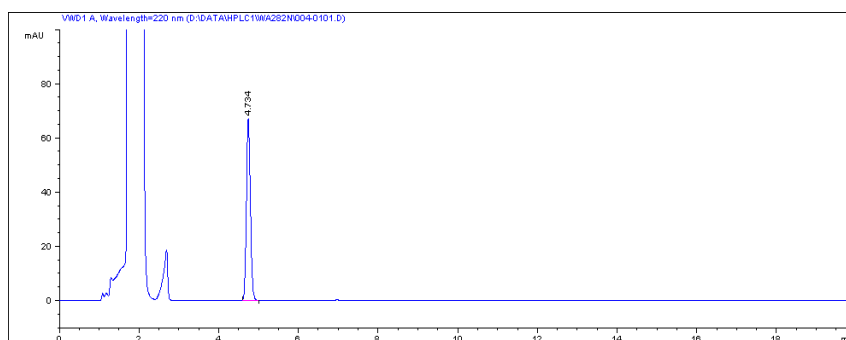
Reference solution: Dissolve and dilute an accurately weighed quantity of morphine CRS in a 5 % acetic acid solution to produce the reference solution of 0.01 mg/mL.

### Chromatographic conditions

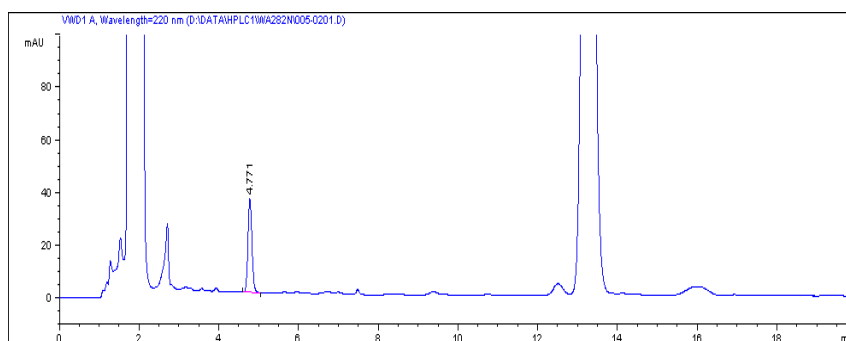
- Column: Agilent ZORBAX Eclipse XDB-C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate:0.0025 mol/L sodium heptanesulfonate solution:acetonitrile=18:18:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA282N004-0101



The chromatogram of the test solution--- HPLC1\ WA282N005-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Morphine	4.77	250.9	11316	/	1.09

# Compound Glycyrrhiza Oral Solution – 复方甘草口服溶液

## Guaifenesin – Method number WA283

### Assay

Test solution: Using a column packed with octadecylsilane bonded silica gel, wash the column with 15 mL of a mixture of methanol-water (3:1) followed by 5 mL of water, then wash the column with an ammonia solution of about pH 9 until the eluent has about pH 9. Treat a quantity ultrasonically for 10 minutes and mix well. Accurately apply 0.5 mL to the washed column, add drop-wise a quantity ammonia TS to adjust the solution in the column to about pH 9, mix well, rinse with 20 mL of water when no more solvent elutes. Elute with 5 % acetic acid solution, collect the eluent in a 5 mL volumetric flask to volume, mix well and use as the test solution.

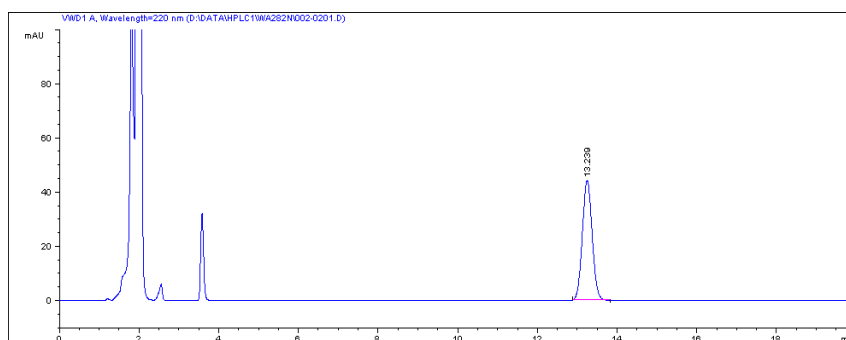
Reference solution: Dissolve and dilute an accurately weighed quantity of guaifenesin CRS with a 5 % acetic acid solution containing 30 % methanol to produce the reference solution of 0.01 mg/mL.

### Chromatographic conditions

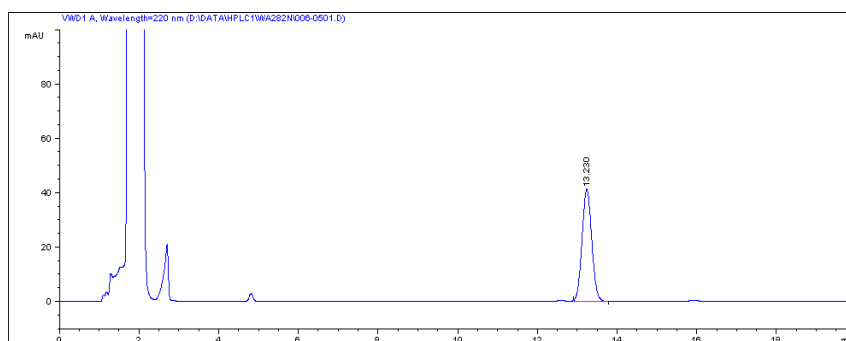
- Column: Agilent ZORBAX Eclipse XDB-C8 4.6×150 mm, 5 µm (993967-906)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate:0.0025 mol/L sodium heptanesulfonate solution: acetonitrile = 18:18:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA282N002-0201



The chromatogram of the test solution--- HPLC1\ WA282N006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Guaifenesin	13.23	698.7	14117	/	1.05

# Compound Glycyrrhiza Tablets – 复方甘草片

Morphine – Method number WR173

## Assay

Test solution: Using a column packed with octadecylsilane bonded silica gel, wash the column with 15 mL of a mixture of methanol-water (3:1) followed by 5 mL of water, then wash the column with an ammonia solution of about pH 9 until the eluent has about pH 9. Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 10 tablets, in a conical flask, accurately add 90 mL of water, treat ultrasonically for 5 minutes. Accurately add 10 mL of dilute hydrochloride (6M), mix well and treat ultrasonically for 20 minutes, allow to cool to room temperature and filter. Accurately apply 1.0 mL to the washed column, add drop-wise ammonia TS to adjust the solution in the column to about pH 9, mix well, rinse with 20 mL of water when no more solvent elutes. Elute with 5 % acetic acid solution containing 2 % methanol, collect the eluent in a 5 mL of volumetric flask to volume, mix well and use as the test solution.

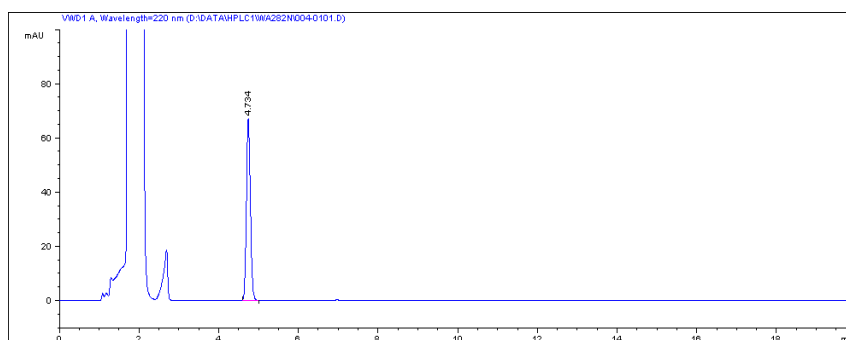
Reference solution: Dissolve and dilute an accurately weighed quantity of morphine CRS with 5 % acetic acid solution containing 2 % methanol to produce the reference solution of 0.01 mg/mL.

## Chromatographic conditions

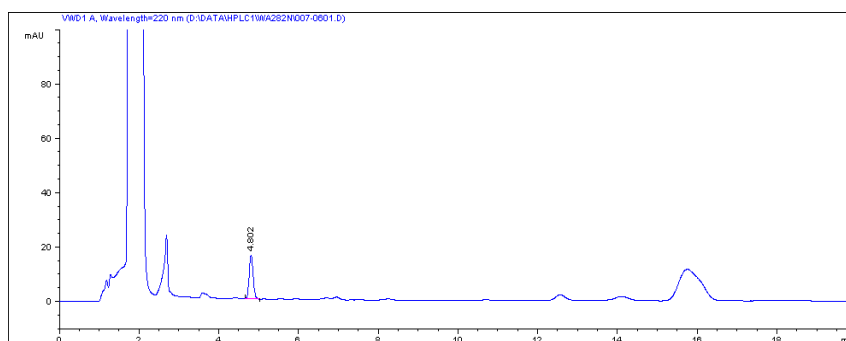
- Column: Agilent ZORBAX Eclipse XDB-C8 4.6×150 mm, 5 µm (993967-906)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate:0.0025 mol/L sodium heptanesulfonate solution: acetonitrile = 18:18:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA282N004-0101



The chromatogram of the test solution--- HPLC1\WA282N005-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Morphine	4.80	110.3	11464	/	1.08

# Compound Sulfamethoxazole oral suspension

Sulfamethoxazole (100025-199503), Trimethoprim (100031-200304) – Method number WA121  
复方磺胺甲噁唑口服混悬液

## Assay

### Test solution

measure accurately 5 mL of the well-mixed suspension to a 100 mL volumetric flask with a “to contain” pipette, wash the inner wall of pipette with several portions of methanol, and transfer the washings to the same flask, add a quantity of methanol and shake to dissolve, dilute to volume with methanol, mix well and filter. Measure accurately 2 mL of the successive filtrate into 50 mL volumetric flask or 25 mL volumetric flask, dilute with the mobile phase to volume and mix well.

### Reference solution

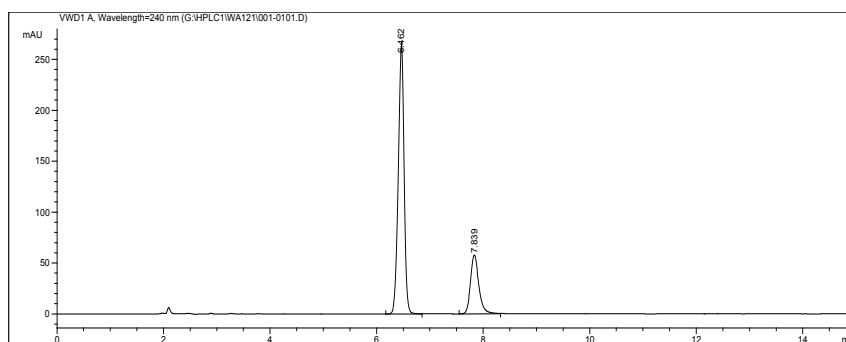
dissolve an accurately weighed quantity of sulfamethoxazole CRS and trimethoprim CRS with a quantity of methanol and dilute with the mobile phase to produce a solution of 0.16 mg of sulfamethoxazole and 0.032 mg of trimethoprim per mL.

## Chromatographic conditions

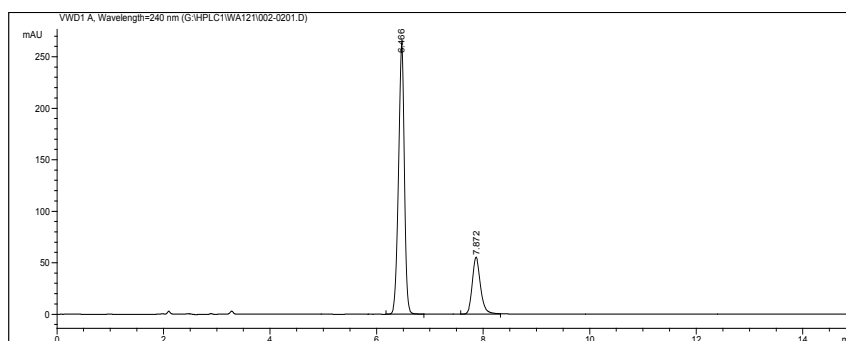
- Column : Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: acetonitrile:0.1 % triethylamine (pH 6.30)= 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA121\001-0101



The chromatogram of the test solution --- HPLC1\WA121\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Sulfamethoxazole	6.47	2022.8	16161	/	0.97
Trimethoprim	7.87	598.1	13383	5.90	1.20



# Compound Sulfamethoxazole Tablets – 复方磺胺甲噁唑片

Sulfamethoxazole (100025-199503)

Trimethoprim (100031-200304) – Method number WA122

## Assay

Test solution: Accurately measure 5 mL of the well-mixed suspension in a 100 mL volumetric flask using a pipette, wash the inner wall of pipette with several portions of methanol, transfer the washings to the same flask, add a quantity of methanol and shake to dissolve, dilute to volume with methanol, mix well and filter. Accurately measure 2 mL of the filtrate in a 50 mL or 25 mL volumetric flask, dilute with mobile phase to volume and mix well.

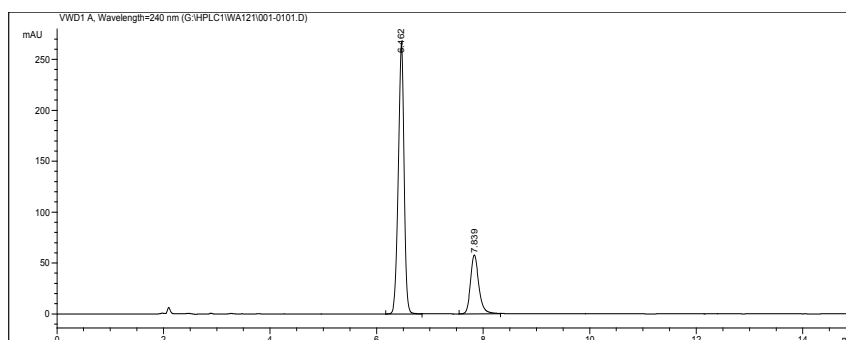
Reference solution: Dissolve an accurately weighed quantity of sulfamethoxazole CRS and trimethoprim CRS with a quantity of methanol and dilute with mobile phase to produce a reference solution of 0.16 mg of sulfamethoxazole and 0.032 mg of trimethoprim per mL.

## Chromatographic conditions

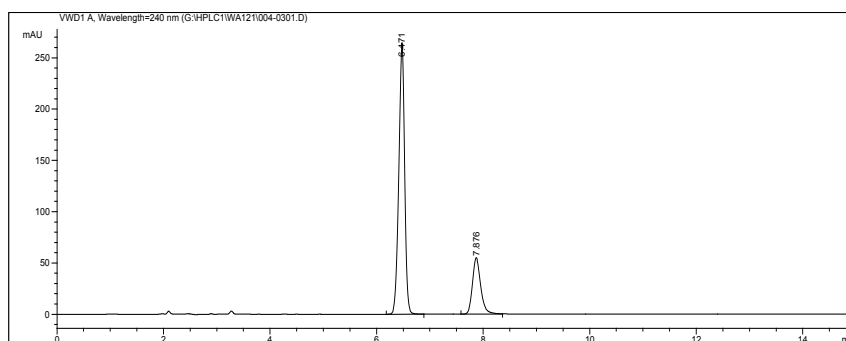
- Column : Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile:0.1 % triethylamine (pH 6.30) = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA121\001-0101



The chromatogram of the test solution--- HPLC1\WA121\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Sulfamethoxazole	6.47	2023.2	15759	/	0.97
Trimethoprim	7.88	598.1	13396	5.9	1.20

# Compound Ketoconazole Cream – 复方酮康唑乳膏

Ketoconazole (0294-9801)

Clobetasol Propionate (10302-0001 ) – Method number WA285

## Assay

Test solution: Accurately weigh about 4 g of cream and add a quantity of anhydrous ethanol. Heat in a water bath at 80 °C to dissolve the ketoconazole and clobetasol propionate, transfer thoroughly to a 50 mL volumetric flask with anhydrous ethanol, allow to cool to room temperature, dilute to volume with anhydrous ethanol and mix well. Cool in an ice bath for at least 2 hours. Filter rapidly, allow the filtrate to stand at room temperature for 15 minutes and use as the test solution.

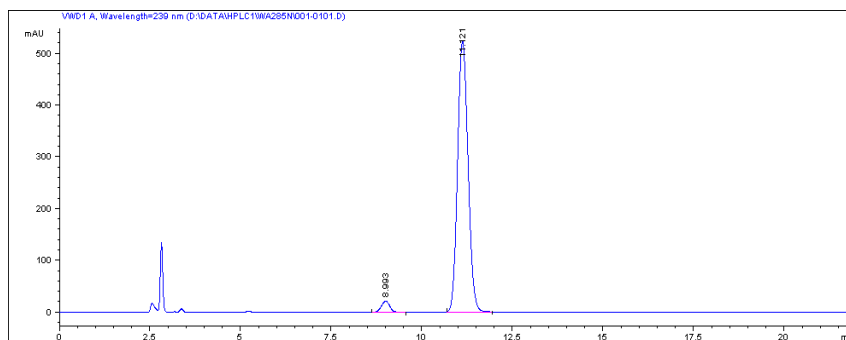
Reference solution: Accurately weigh a quantity of ketoconazole CRS and clobetasol propionate CRS, add anhydrous ethanol to produce a reference solution of 0.8 mg of ketoconazole CRS and 20 µg of clobetasol propionate CRS per mL.

## Chromatographic conditions

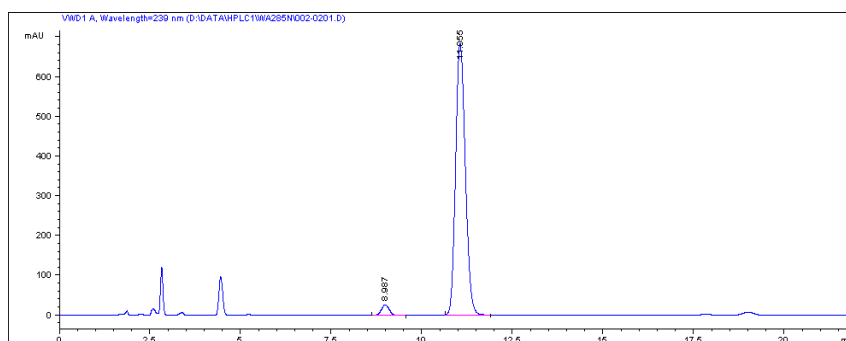
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water=74:26
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 239nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA285N001-0101



The chromatogram of the test solution --- HPLC1WA285N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clobetasol Propionate	8.99	393.4	8600	/	1.04
Ketoconazole	11.06	12794.9	8119	4.7	1.13

# Glycerol and Fructose Injection – 甘油果糖注射液

Glycerol Fructose (100231-200303) Sodium Chloride – Method number WA020

## Assay

Internal standard solution: Accurately measure 15 mL of 1, 2-propylene glycol in a 100 mL volumetric flask, dilute to volume with mobile phase and mix well.

### Test solution:

Accurately measure 5 mL of the injection fluid and 10 mL of internal standard solution in a 100 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the test solution.

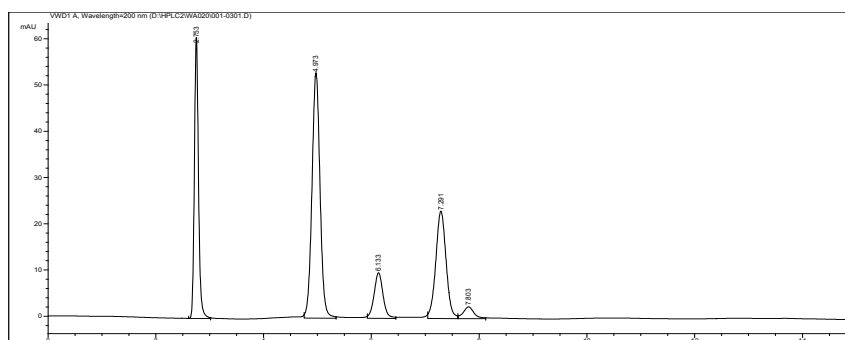
Reference solution: Dissolve accurately weighed quantities of sodium chloride CRS, fructose CRS and glycerol CRS in water, dilute with the mobile phase to produce a reference solution of 9, 50 and 100 mg per mL, respectively.

## Chromatographic conditions

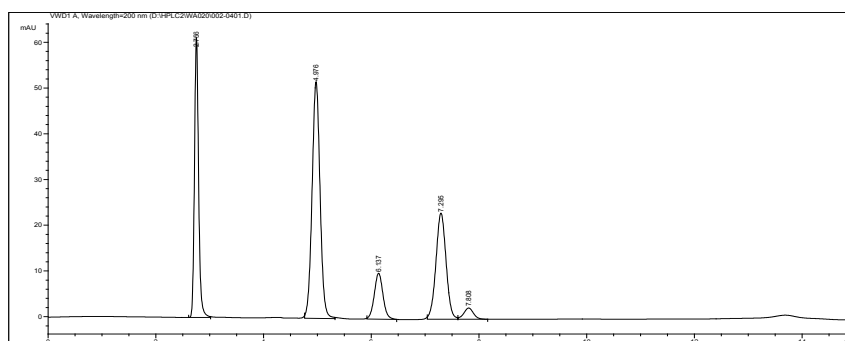
- Column: packed with strong cation-exchange resin consisting of sulfonated cross-lined styrene-divinylbenzene copolymer in the hydrogen form (HC-75H+)
- Mobile phase: 0.04 mol/L phosphoric acid solution
- Flow rate: 0.4 mL/min
- Injection volume: 10  $\mu$ L
- Column temperature: 50  $^{\circ}$ C
- Detector wavelength: 200 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WA020\001-0301.D



The chromatogram of the test solution --- HPLC1\WA020\002-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Sodium Chloride	2.76	325.7	6562	/	1.16
Fructose	4.98	531.7	5686	11.08	1.03
Glycerol	6.14	112.3	7231	4.2	1.03
1,2-propanediol(internal standard)	7.30	303.7	7445	3.7	1.01

# Glipizide – 格列吡嗪

Glipizide (100281-0001) – Method number WA144

## Assay

Test solution: Accurately weigh about 25 mg of the substance in a 50 mL volumetric flask, dissolve, in 25 mL of methanol, dilute with 0.1 mol/L sodium dihydrogen phosphate solution to volume, mix well and use as the test solution.

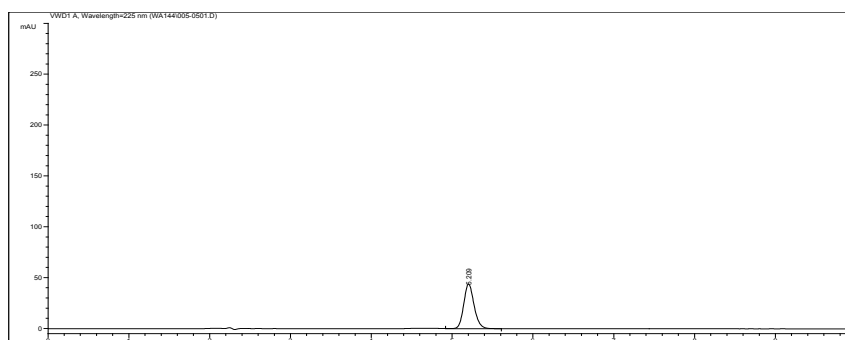
Reference solution: Accurately measure 1 mL of test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

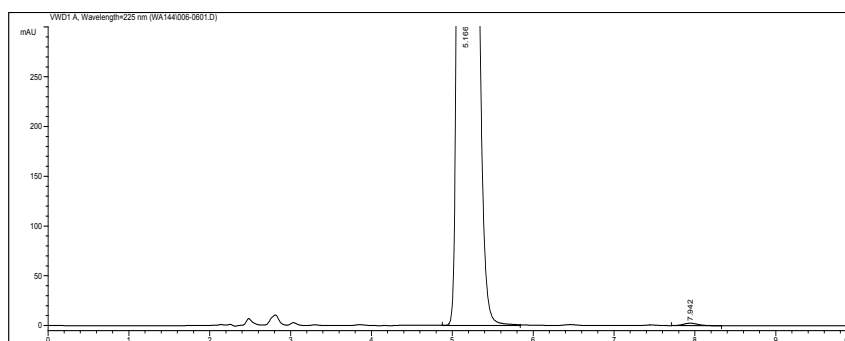
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.1 mol/L sodium dihydrogen phosphate solution (adjust pH to 6.00±0.05 with 2.0 mol/L sodium hydroxide):methanol = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA144\005-0501



The chromatogram of the test solution--- HPLC1\ WA144\006-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Glipizide	5.17	36790.3	5765	/	1.27
Impurity	7.94	30.7	9508	9.3	1.09

# Glipizide Capsules – 格列吡嗪胶囊

Glipizide (100281-0001) – Method number WA146

## Assay

**Test solution:** Accurately weigh 20 capsules and mix the contents of the capsules well. Accurately weigh a quantity, equivalent to about 5mg of glipizide, in a 100 mL volumetric flask, add 50 mL of methanol, treat ultrasonically for 15 minutes to dissolve the glipizide, dilute with 0.1 mol/L sodium dihydrogen phosphate solution to volume, shake well, filter and use the filtrate as the test solution.

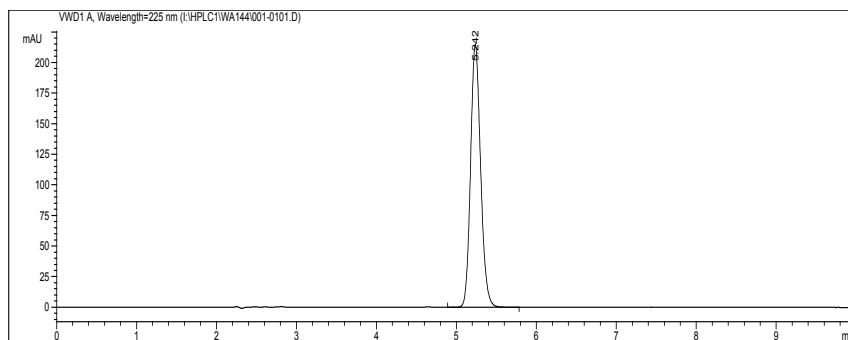
**Reference solution:** Accurately weigh about 25 mg of glipizide CRS in a 50 mL volumetric flask, add a quantity of methanol, shake thoroughly to dissolve the glipizide, dilute to volume with methanol and mix well. Accurately measure 5 mL in another 50 mL volumetric flask, add 20 mL methanol and dilute with 0.1 mol/L sodium dihydrogen phosphate solution to volume, mix well and use as the reference solution.

## Chromatographic conditions

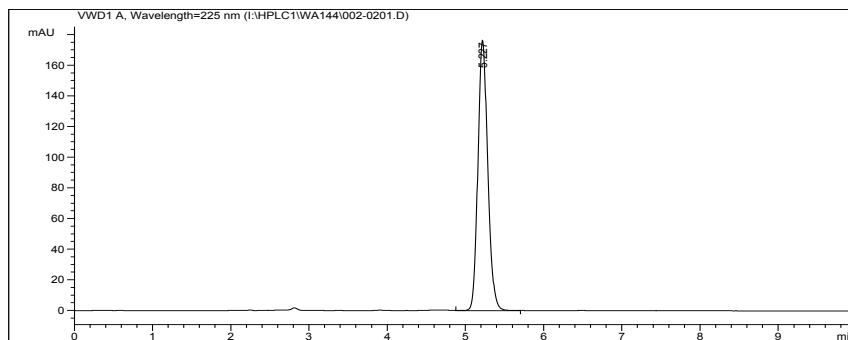
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.1 mol/L sodium dihydrogen phosphate solution (adjust pH to 6.00±0.05 with 2.0 mol/L sodium hydroxide):methanol = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA144\001-0101



The chromatogram of the test solution --- HPLC1\ WA144\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Glipizide	5.23	1548.9	7301	/	1.09

# Glipizide Capsules – 格列吡嗪胶囊

Glipizide (100281-0001) – Method number WA146

## Assay

**Test solution:** Accurately weigh a quantity of the contents of the capsules, equivalent to about 25 mg of glipizide, in a 50 mL volumetric flask, add 25 mL of methanol, shake to dissolve the glipizide, dilute with 0.1 mol/L sodium dihydrogen phosphate solution to volume, mix well, filter and use the filtrate as the test solution.

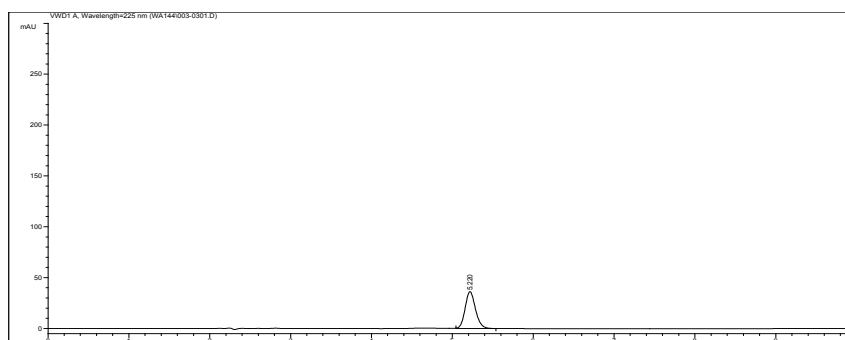
**Reference solution:** Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, add mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

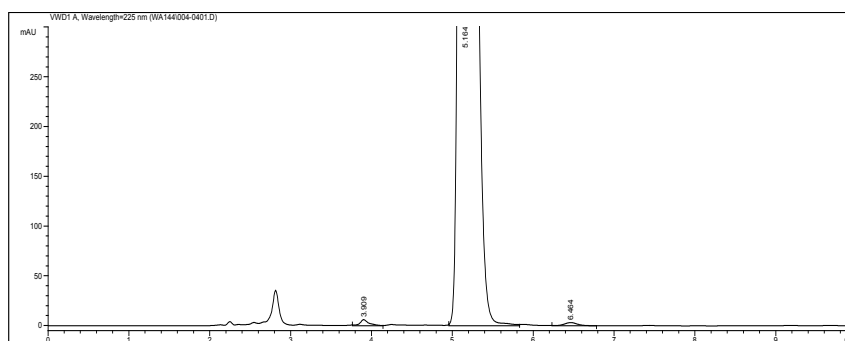
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.1 mol/L sodium dihydrogen phosphate solution (adjust pH to 6.00±0.05 with 2.0 mol/L sodium hydroxide):methanol = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA144\003-0301



The chromatogram of the test solution--- HPLC1\ WA144\004-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Glipizide	5.16	30978.4	6968	6.0	1.32
Impurity1	3.91	49.0	8765	/	/
Impurity2	6.46	37.2	8337	4.9	0.97

# Glipizide Tablets – 格列吡嗪片

## Glipizide (10281-0001) – Method number WA145

### Assay

Test solution: Grind the tablets to a fine powder, accurately weigh a quantity of the powder, equivalent to 25 mg of glipizide, in a 50 mL volumetric flask, add 25 mL of methanol, dilute with 0.1 mol/L sodium dihydrogen phosphate solution to volume, filter and use the filtrate as the test solution.

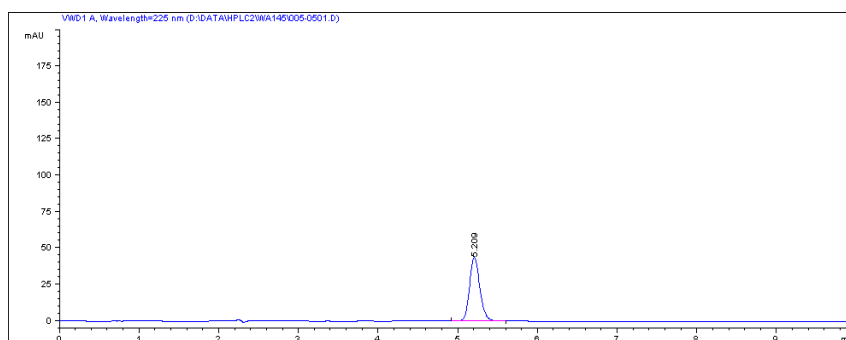
Reference solution: Accurately measure 1 mL of test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

### Chromatographic conditions

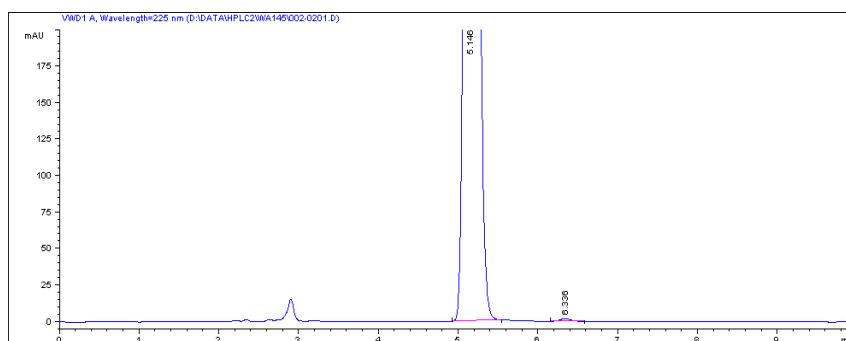
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.1 mol/L sodium dihydrogen phosphate solution (adjust pH to 6.00±0.05 with 2.0 mol/L sodium hydroxide):methanol = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA145\005-0501



The chromatogram of the test solution---HPLC2\WA145\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Glipizide	5.15	15064.1	8557	/	1.18
Impurity	6.34	20.6	9036	4.8	0.99

# Puerarin – 葛根素

Puerarin (11752-200210) – Method number WA313

## Assay

Test solution: Dissolve a quantity in mobile phase to produce the test solution of 0.4 mg/mL.

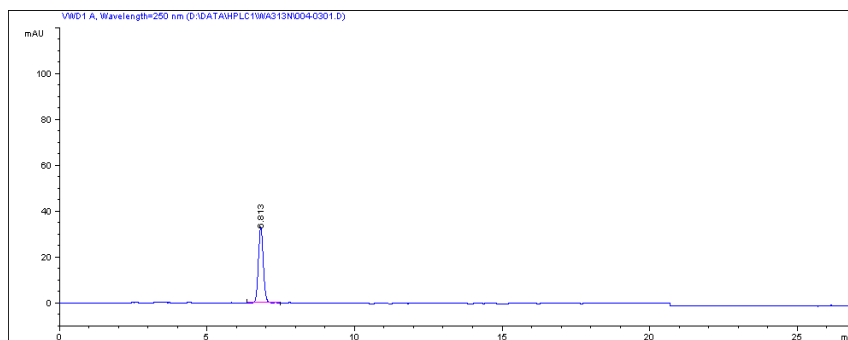
Reference solution: Dissolve a quantity in mobile phase to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

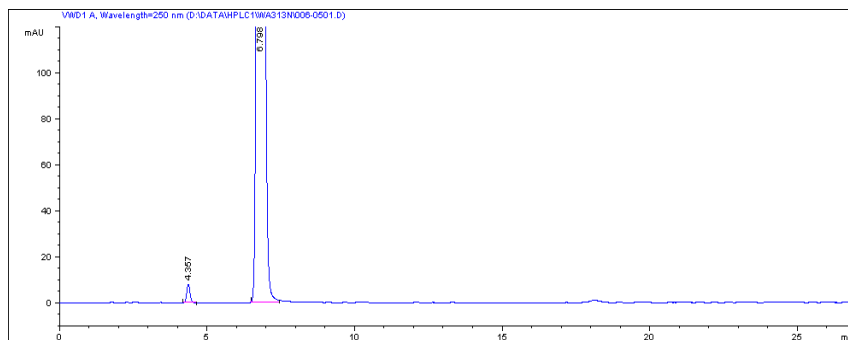
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:0.1 % citric acid = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 250 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA313N004-0301



The chromatogram of the test solution--- HPLC1\WA313N006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Puerarin	6.80	15571.3	8624	9.9	1.10
Impurity	4.36	62.1	7540	/	1.07



# Puerarin and Sodium Chloride Injection – 葛根素氯化钠注射液

## Puerarin (11752-200210) – Method number WA316

### Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce a test solution of 0.05 mg/mL.

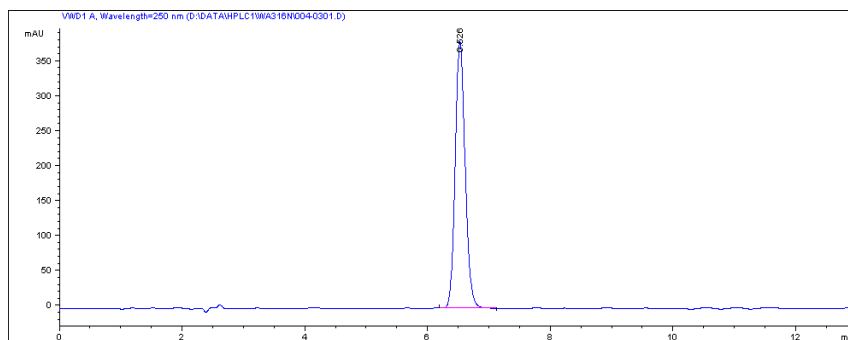
Reference solution: Use puerarin CRS to produce the reference solution, in which the concentration is equivalent to the test solution.

### Chromatographic conditions

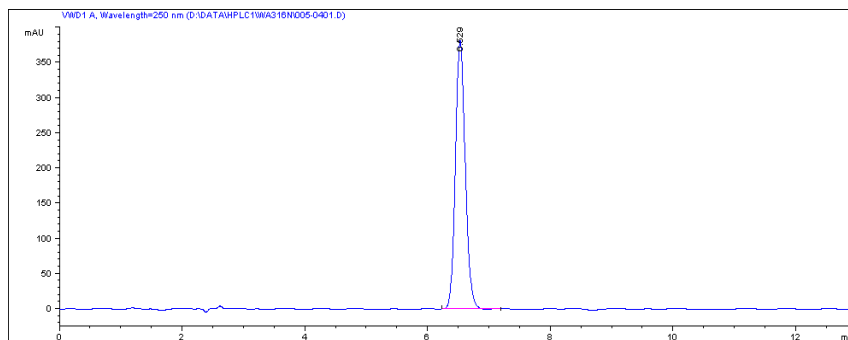
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:0.1 % citric acid = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 250 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA316\N004-0301



The chromatogram of the test solution--- HPLC1\WA316\N005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Puerarin	6.53	4287.2	7957	/	1.09

# Puerarin and Sodium Chloride Injection – 葛根素氯化钠注射液

## Puerarin (11752-200210) – Method number WA316

### Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce a test solution of 0.4 mg/mL.

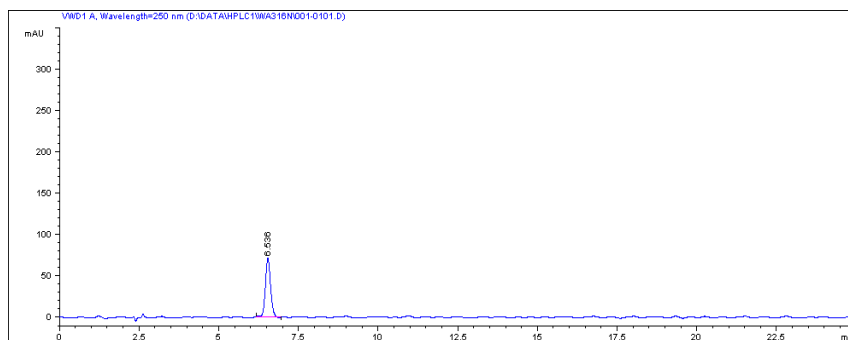
Reference solution: Dissolve a quantity in mobile phase to produce a reference solution of 12 µg/mL.

### Chromatographic conditions

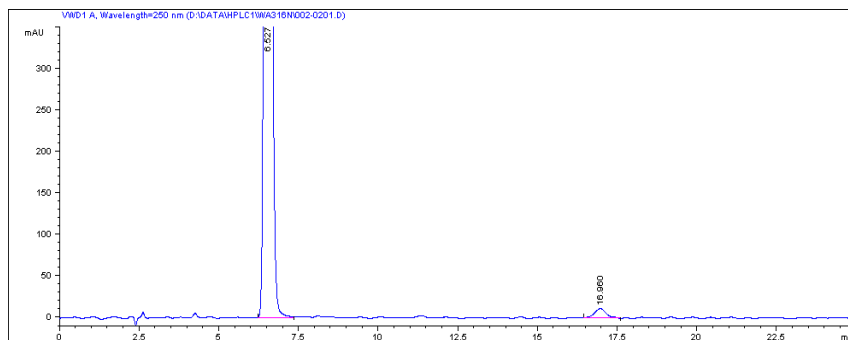
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:0.1 % citric acid = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 250 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA316N001-0101



The chromatogram of the test solution--- HPLC1\WA316N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Puerarin	6.53	34127.1	7732	/	1.12
Impurity	16.96	310.9	11120	22.2	1.04

# Puerarin and Glucose Injection – 葛根素葡萄糖注射液

Puerarin (11752-200210) – Method number WA315

## Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce a test solution of 0.05 mg/mL.

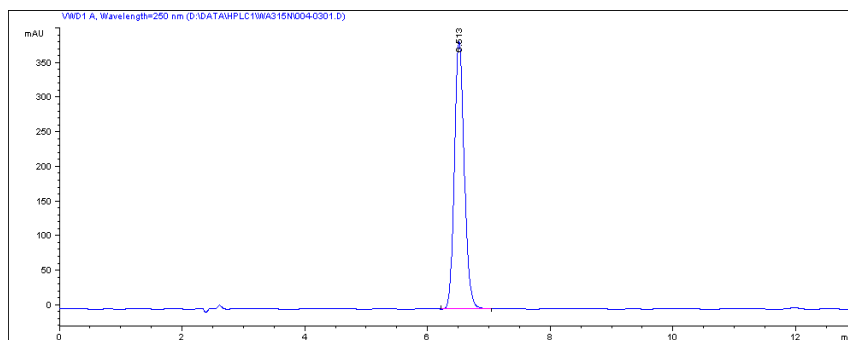
Reference solution: Use puerarin CRS to produce the reference solution, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

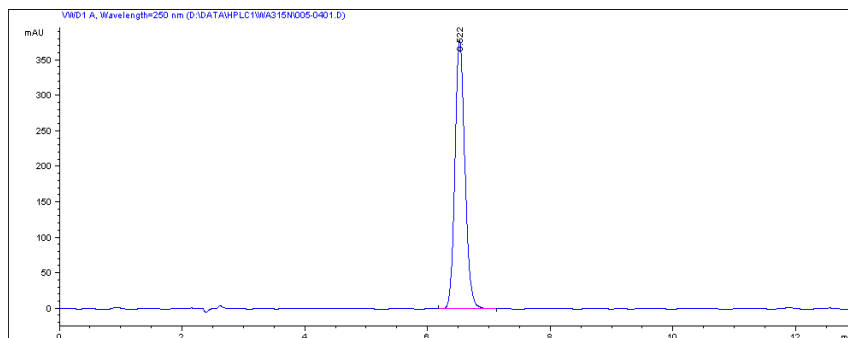
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:0.1 % citric acid = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 250 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA315\N004-0301



The chromatogram of the test solution--- HPLC1\WA315\N005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Puerarin	6.52	4257.5	7720	/	1.10

# Puerarin and Glucose Injection – 葛根素葡萄糖注射液

Puerarin (11752-200210) – Method number WA315

## Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce a test solution of 0.4 mg/mL.

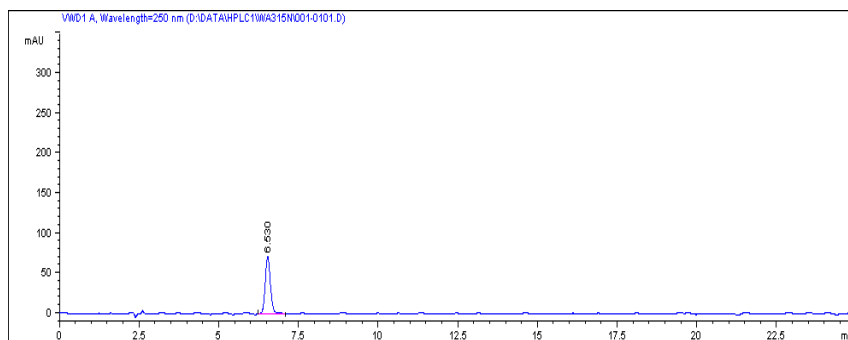
Reference solution: Dissolve a quantity in mobile phase to produce a reference solution of 12 µg/mL.

## Chromatographic conditions

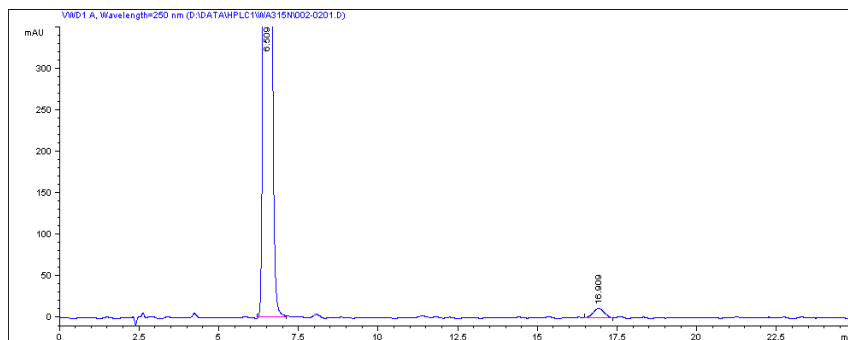
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:0.1 %citric acid=30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 250 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA315N001-0101



The chromatogram of the test solution--- HPLC1\WA315N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Puerarin	6.51	34005.9	8133	/	1.13
Impurity	16.91	278.6	11196	22.4	0.93

# Puerarin Injection – 葛根素注射液

## Puerarin (11752-200210) – Method number WA314

### Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce a test solution of 0.05 mg/mL.

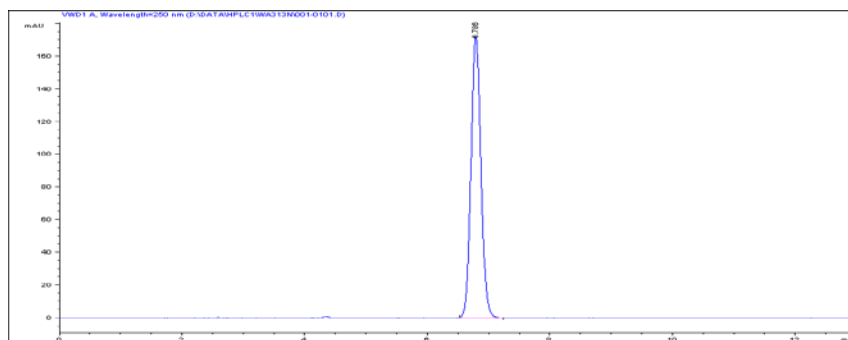
Reference solution: Use puerarin CRS to produce the reference solution, in which the concentration is equivalent to the test solution.

### Chromatographic conditions

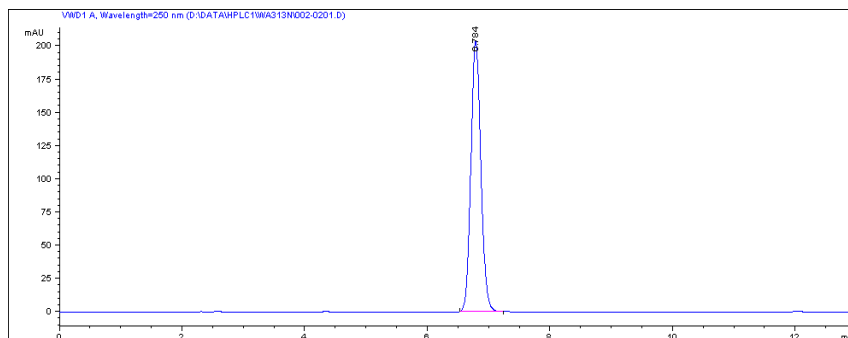
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:0.1 % citric acid = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 250 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA313N001-0101



The chromatogram of the test solution--- HPLC1\WA313N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Puerarin	6.79	2321.3	8135	/	1.08

# Puerarin Injection – 葛根素注射液

## Puerarin (11752-200210) – Method number WA314

### Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce a test solution of 0.4 mg/mL.

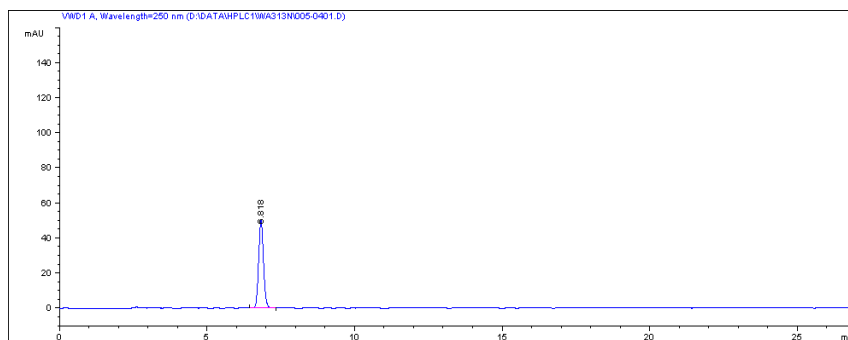
Reference solution: Dissolve a quantity in mobile phase to produce a reference solution of 12 µg/mL.

### Chromatographic conditions

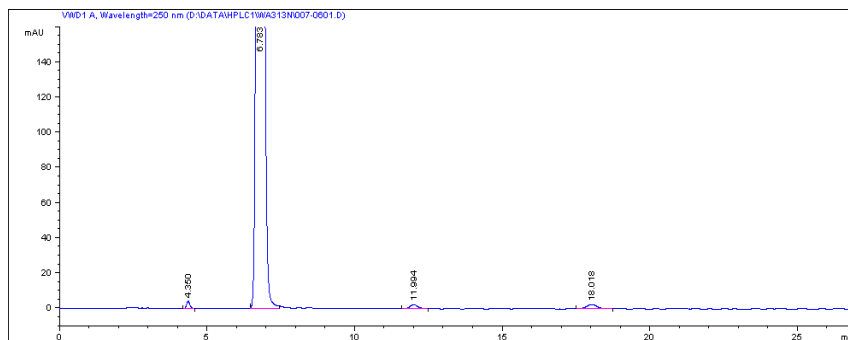
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:0.1 % citric acid = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 250 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA313N\005-0401



The chromatogram of the test solution--- HPLC1\WA313N\007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Puerarin	6.78	18697.7	7903	9.6	1.09
Impurity1	4.35	34.9	7314	/	1.24
Impurity2	11.99	43.3	9886	13.2	1.14
Impurity3	18.02	64.4	12234	10.6	1.11

# Ganciclovir – 更昔洛韦

Ganciclovir(100380-200301) Guanine (140631-200302) – Method number WA074

## Assay

Test solution: Accurately weigh about 15 mg in a 50ml volumetric flask, add 1 mL of 0.4 % sodium hydroxide solution, dilute with mobile phase to volume, mix well and use as the test solution.

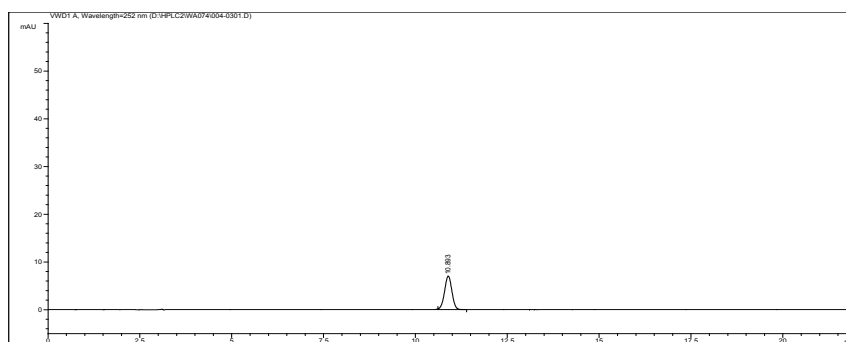
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce a reference solution of 3 µg/mL.

## Chromatographic conditions

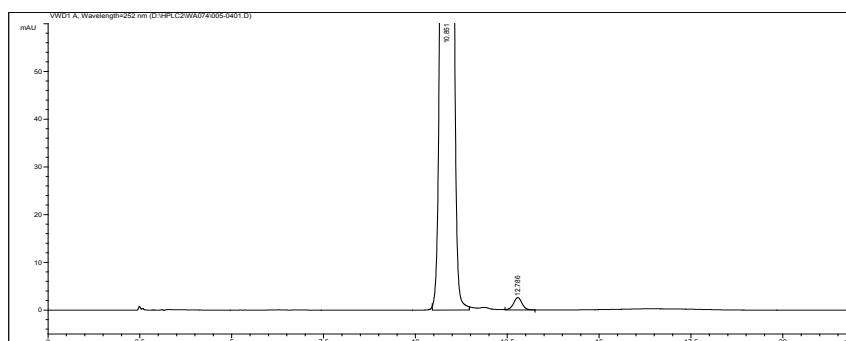
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm
- (880975-914)
- Mobile phase: water : methanol =95:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 252 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of Ganciclovir---HPLC2WA074004-0301



The chromatogram of the test solution--- HPLC2WA074005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ganciclovir	10.85	9242.8	14304	/	1.04
guanine	12.79	41.6	15380	4.98	0.98

# Ganciclovir and Sodium Chloride Injection – 更昔洛韦氯化钠注射液

## Ganciclovir (100380-200301) Guanine (140631-200302) – Method number WA075

### Assay

**Test solution:** Dilute an accurately measured quantity of the injection fluid with mobile phase to produce a solution containing 40 µg of ganciclovir per mL as the test solution.

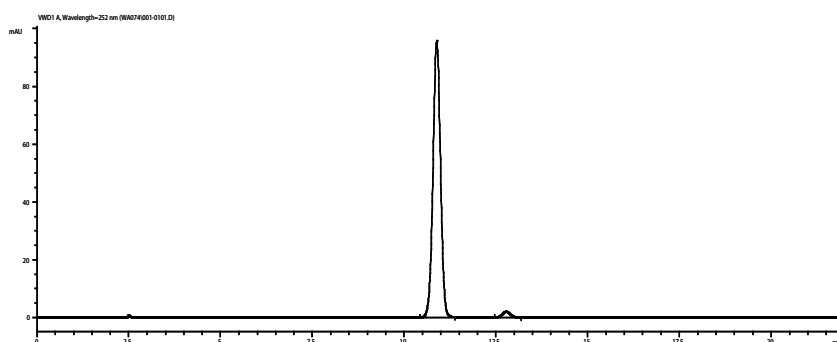
**Reference solution:** Accurately weigh about 25 mg of ganciclovir CRS dried to constant weight at 105 °C in a 25 mL volumetric flask, add 1 mL of 0.4 % sodium hydroxide solution, dilute with the mobile phase to volume, mix well, dilute an accurately measured quantity with mobile phase to produce a reference solution containing 40 µg of ganciclovir CRS per mL.

### Chromatographic conditions

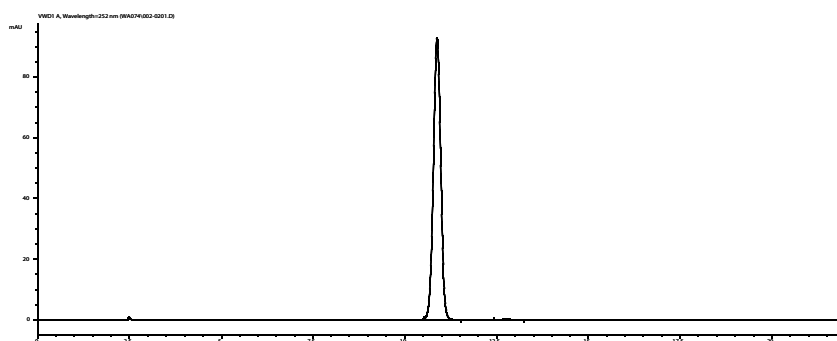
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol =95:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature : 30 °C
- Detector wavelength: 252 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the system suitability ---HPLC2WA0074001-0101



The chromatogram of the test solution --- HPLC2 WA074002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ganciclovir	10.89	1349.0	14408	/	0.99
Guanine	12.78	53.3	15992	4.9	1.03



# Ganciclovir and Sodium Chloride Injection – 更昔洛韦氯化钠注射液

## Ganciclovir (100380-200301) Guanine (140631-200302) – Method number WA075

### Assay

Test solution: Dilute a quantity with mobile phase to produce a test solution containing 0.3 mg of ganciclovir per mL.

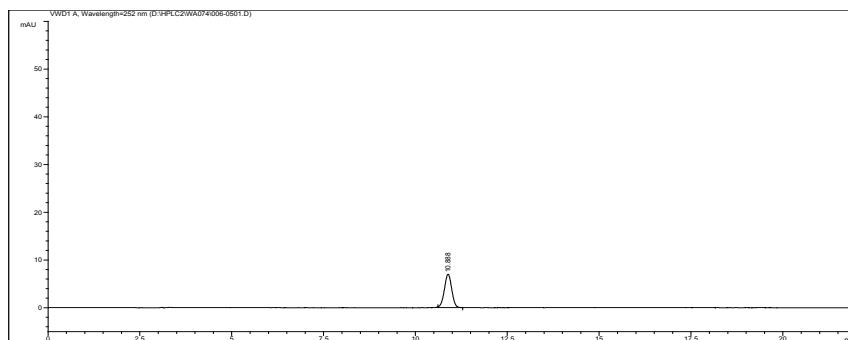
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce a reference solution of 3 µg/mL.

### Chromatographic conditions

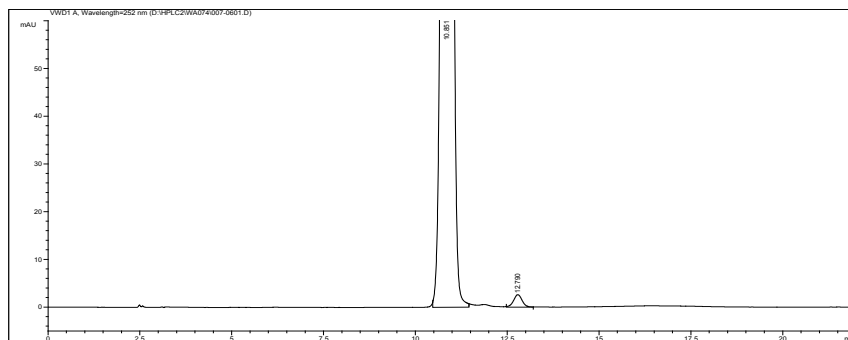
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol =95:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature : 30 °C
- Detector wavelength: 252 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA074\006-0501



The chromatogram of the test solution--- HPLC2\WA074\007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ganciclovir	10.85	9257.2	14304	/	1.06
Guanine	12.79	42.5	15390	5.0	0.97

# Halcinonide – 哈西奈德

Halcinonide (10146-9502)– Method number WR075

## Assay

Test solution: Accurately weigh about 12.5 mg of the substance in a 25ml volumetric flask, add 19 mL of methanol to dissolve the halcinonide, dilute with water to volume, mix well and use as the test solution.

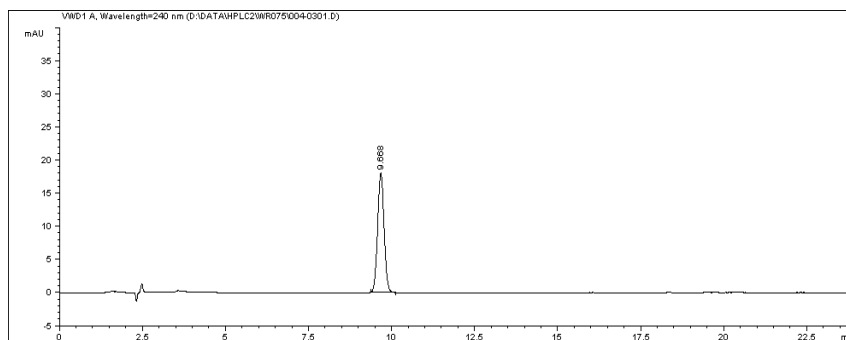
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well use as the reference solution.

## Chromatographic conditions

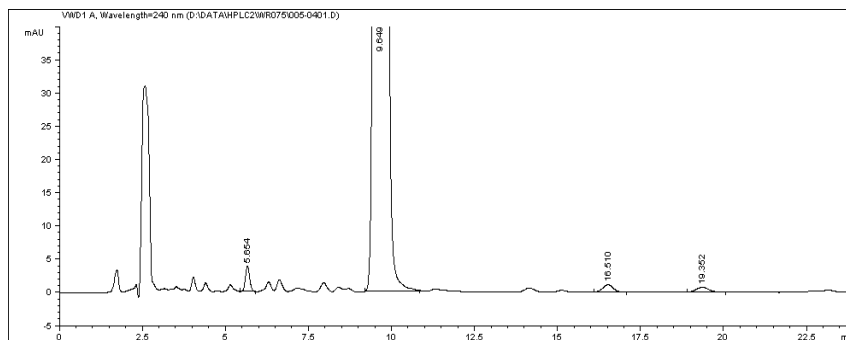
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: methanol-water = 76:24
- Flow rate: 1.0 mL/min
- Injection volume: 20 μL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR075004-0301.D



The chromatogram of the test solution --- HPLC2WR075005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Halcinonide	9.65	23222.4	11310	13.4	1.06
Impurity1	5.65	34.6	9367	/	1.08
Impurity2	16.51	24.8	13273	14.6	1.00
Impurity3	19.35	19.1	12483	4.5	1.05

# Halcinonide Membrane – 哈西奈德涂膜剂

Halcinonide (10146-9502) – Method number WA113

## Assay

Test solution: Dissolve a quantity of membrane, equivalent to about 2.5 mg of halcinonide, in mobile phase in a 100 mL volumetric flask, dilute with the mobile phase to volume, mix well and use as the test solution.

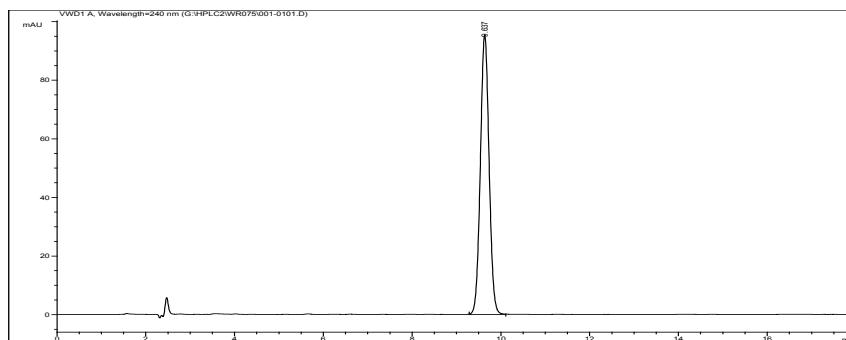
Reference solution: Accurately weigh about 25 mg of halcinonide CRS in a 100 mL volumetric flask, dissolve in 74 mL of methanol, dilute with water to volume, mix well. Accurately measure 5 mL of the solution in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

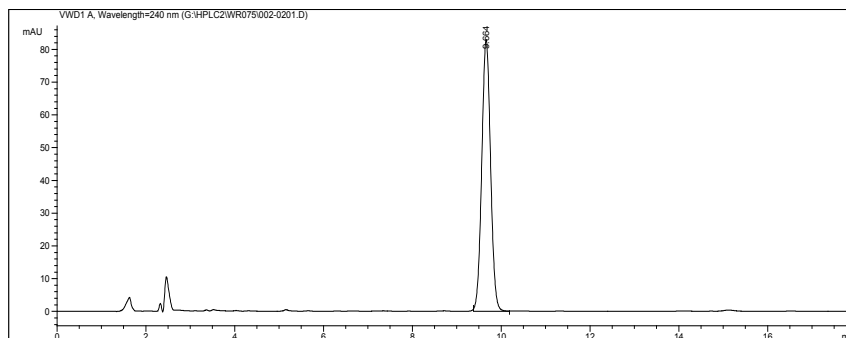
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : water =74:26
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR075001-0101



The chromatogram of the test solution --- HPLC2\WR075002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Halcinonide	9.66	1140.0	11607	/	1.03

# Erythromycin – 红霉素

Erythromycin (130307-200215) – Method number WR032

## Assay

Test solution: Dissolve an accurately weighed quantity in methanol, dilute with a mixture of phosphate BS (pH 7.0) and methanol (15:1) to produce a test solution containing 4 mg/mL.

Reference solution: Dissolve an accurately weighed quantity in methanol, dilute with a mixture of phosphate BS (pH 7.0) and methanol (15:1) to produce a reference solution containing 0.4 mg/mL.

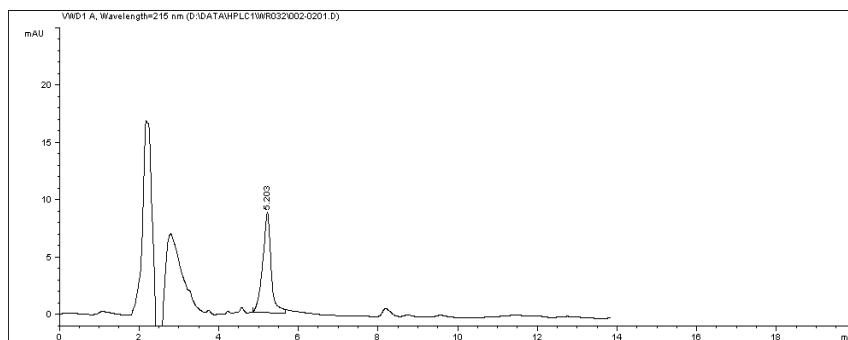
- Mobile phase: 0.2 mol/L ammonium phosphate BS (to 1.15 g of ammonium dihydrogen phosphate add 50 mL of water, adjust pH to 6.5 with triethylamine)-0.2 mol/L tetramethylammonium hydroxide solution (to 14.6 mL of 25 % tetramethylammonium hydroxide add 100 mL of water, adjust pH to 6.5 with phosphoric acid, dilute with water to 200 mL) -acetonitrile-water (5:20:40:35)

## Chromatographic conditions

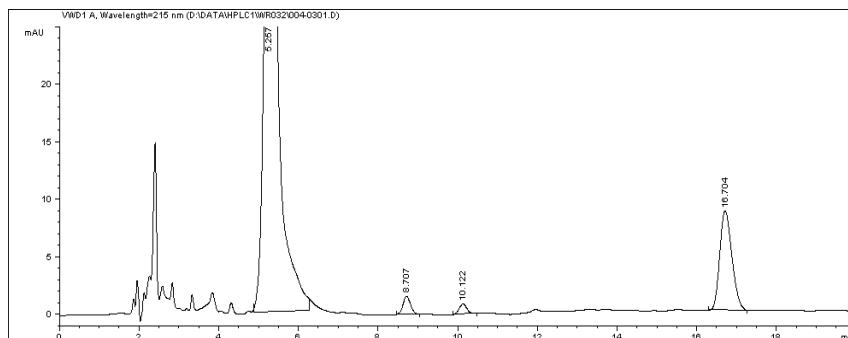
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: see assay
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WR032\002-0201.D



The chromatogram of the test solution--- HPLC1\WR032\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
ErythromycinA	5.26	1488.4	2942	/	1.67
Impurity1	8.71	21.4	10607	9.5	1.12
Impurity2	10.12	12.3	13032	4.1	1.45
Impurity3	16.70	183.4	14193	14.3	1.21

# Erythromycin Enteric-coated Tablets – 红霉素肠溶片

Erythromycin (130307-200215) – Method number WR033

## Assay

Test solution: Remove the coatings from 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.1 g of erythromycin A, add 5 mL of methanol to dissolve the erythromycin, dilute with a mixture of phosphate BS (pH 7.0) and methanol (15:1) to produce a test solution of 4 mg/mL.

Reference solution: Repeat the procedure using erythromycin CRS to produce the reference solution.

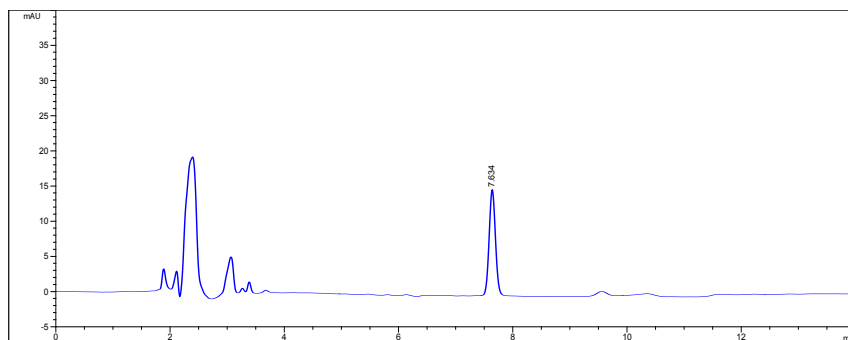
- Mobile phase: 0.2 mol/L ammonium phosphate BS (to 1.15 g of ammonium dihydrogen phosphate add 50 mL of water, adjust pH to 6.5 with triethylamine)-0.2 mol/L tetramethylammonium hydroxide solution (to 14.6 mL of 25 % tetramethylammonium hydroxide add 100 mL of water, adjust pH to 6.5 with phosphoric acid, dilute with water to 200 mL) -acetonitrile-water (5:20:30:45)

## Chromatographic conditions

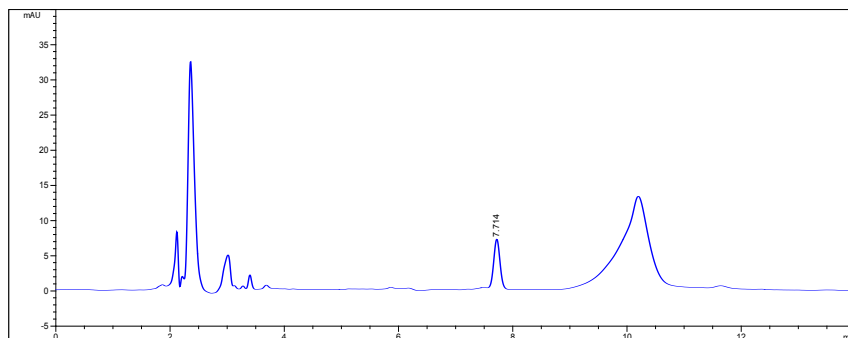
- Column: ZORBAX Eclipse Plus C18 4.6×250 mm, 5 µm (959990-902)
- Mobile phase: see assay
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 25 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2



The chromatogram of the test solution--- HPLC2

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Erythromycin	5.26	1458.6	2074	/	1.67

# Cyclosporine Oral Solution – 环孢素口服溶液

Cyclosporine (30495-200202)– Method number WR066

## Assay

Test solution: Dissolve an accurately weighed quantity in a mixture of methanol-chloroform (4:1) to produce the test solution of 1 mg/mL.

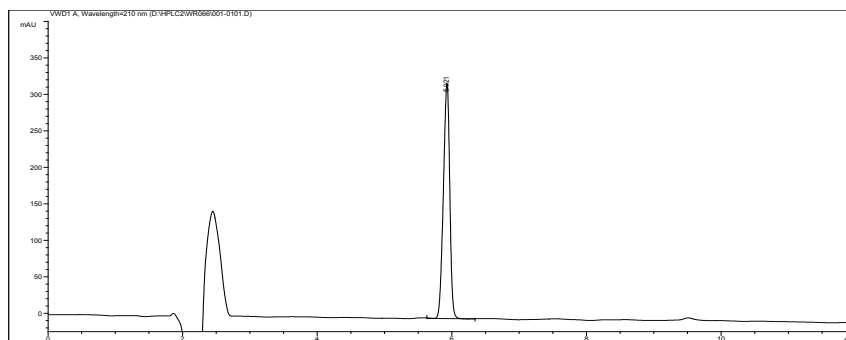
Reference solution: Repeat the procedure using cyclosporine CRS to produce the reference solution.

## Chromatographic conditions

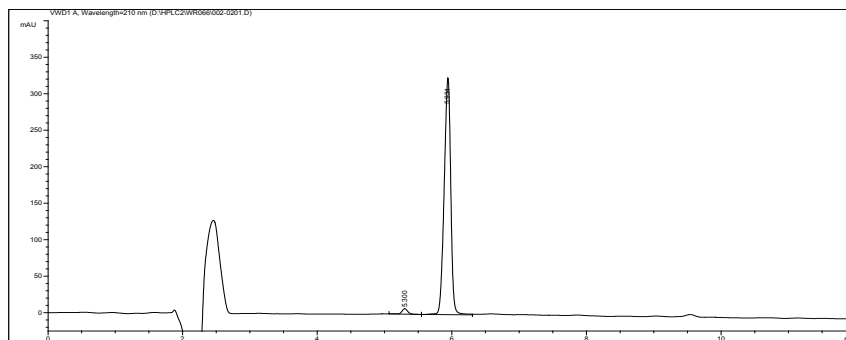
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile-water-phosphoric acid (46:54:0.25)
- Flow rate: 1.0 mL/min
- Injection volume: 3 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR066\001-0101



The chromatogram of the test solution --- HPLC2\WR066\002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cyclosporin	5.93	2194.3	15656	3.72	0.96

# Inosine – 肌昔

Inosine – Method number WA050

## Assay

Test solution: Dissolve a quantity of the substance in water to produce the test solution of 0.5 mg/mL.

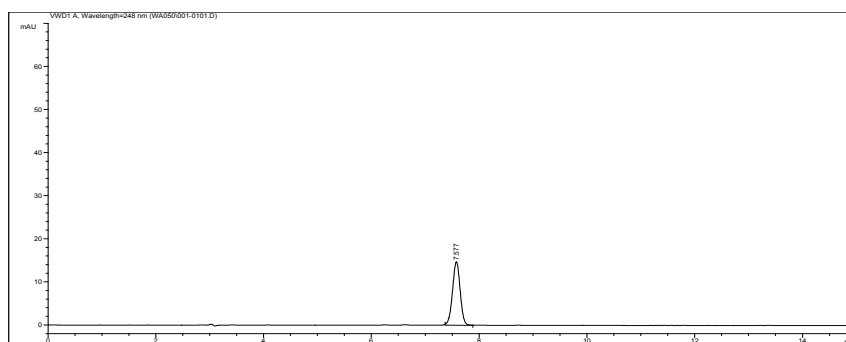
Reference solution: Dilute an accurately measured quantity of the test solution with water to produce the reference solution of 5 µg/mL.

## Chromatographic conditions

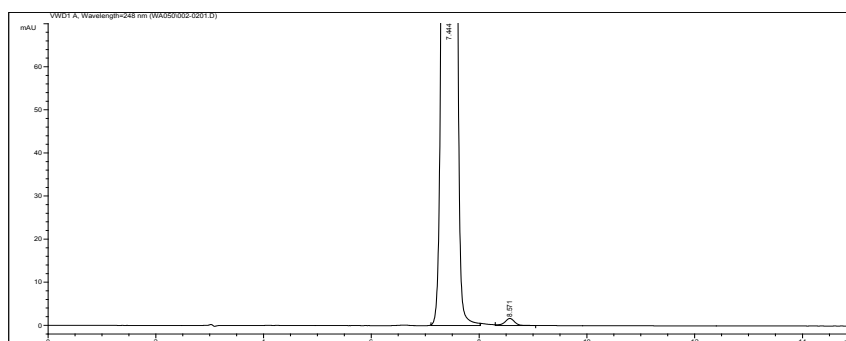
- Column : Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol=90:10
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1WA050001-0101



The chromatogram of the test solution--- HPLC1WA050002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Inosine	7.44	12613.7	13860	/	1.02
Impurity	8.57	21.6	12285	4.0	0.91

# Inosine Capsules – 肌昔胶囊

Inosine – Method number WA054

## Assay

Test solution: Grind the contents of the capsules to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.1g of inosine, in a 100 mL volumetric flask, add about 70 mL of water, shake thoroughly to dissolve the inosine, dilute with water to volume and mix well. Filter and accurately measure 2 mL of the filtrate in a 100 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

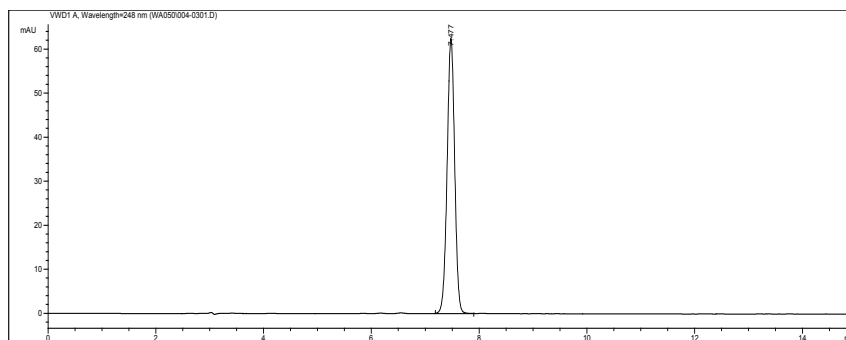
Reference solution: Repeat the procedure using inosine CRS to produce the reference solution.

## Chromatographic conditions

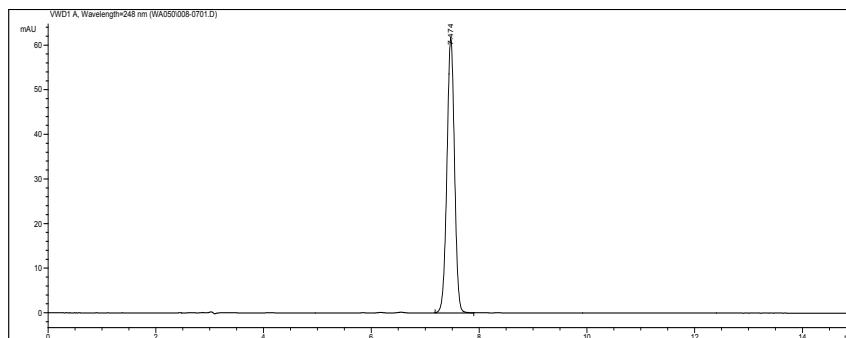
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol =90:10
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA050\004-0301



The chromatogram of the test solution--- HPLC1\ WA050\008-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Inosine	7.47	603.8	13670	/	0.99



# Inosine Oral Solution – 肌昔口服溶液

Inosine – Method number WA051

## Assay

Test solution: Dilute an accurately measured quantity of the oral solution with water to produce a test solution of about 20 µg/mL.

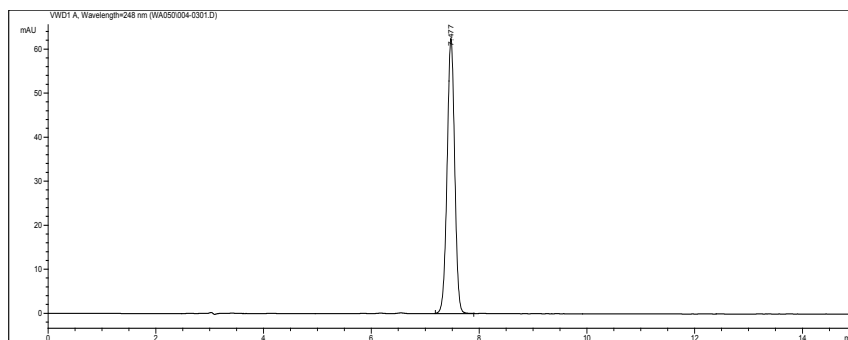
Reference solution: Repeat the procedure using inosine CRS to produce the reference solution.

## Chromatographic conditions

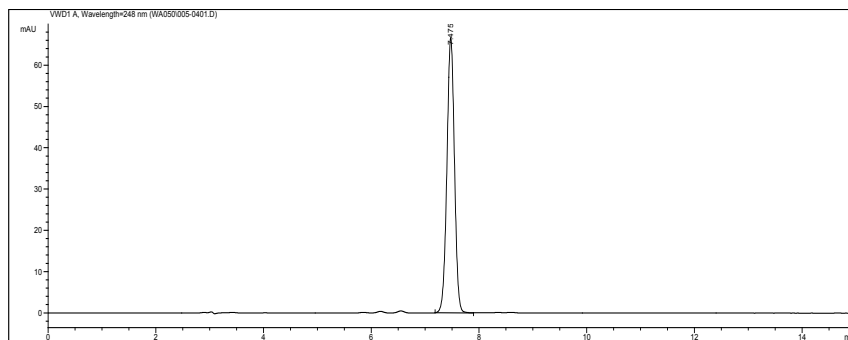
- Column : Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol =90:10
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA050\004-0301



The chromatogram of the test solution--- HPLC1\WA050\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Inosine	7.48	650.8	13676	/	0.99

# Inosine Tablets – 肌昔片

Inosine – Method number WA052

## Assay

Test solution: Remove the coatings from 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.1g of inosine, in a 100 mL volumetric flask, add 70 mL of water, shake thoroughly to dissolve the inosine, dilute with water to volume and mix well. Filter and accurately measure 2 mL of the filtrate in a 100 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

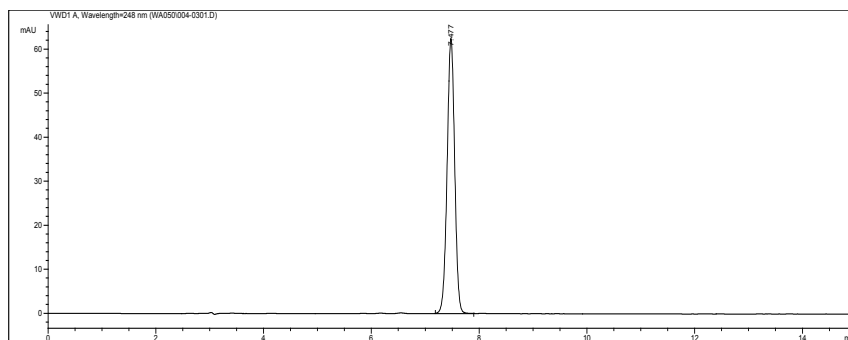
Reference solution: Repeat the procedure using inosine CRS to produce the reference solution.

## Chromatographic conditions

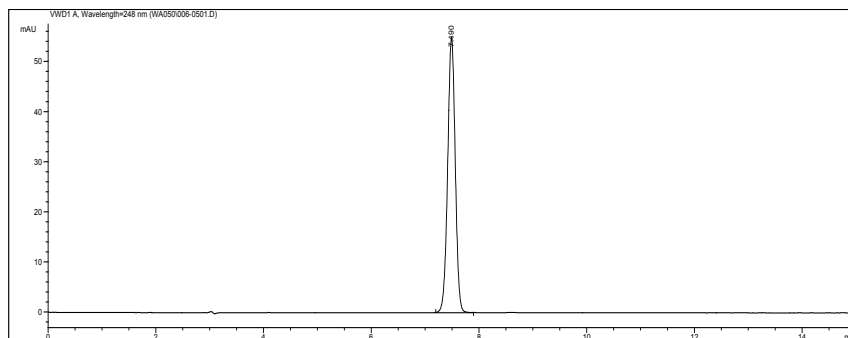
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol =90:10
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA050\004-0301



The chromatogram of the test solution--- HPLC1\ WA050\006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Inosine	7.49	538.0	13157	/	0.99

# Inosine Injection – 肌昔注射液

Inosine – Method number WA053

## Assay

Test solution: Dilute an accurately measured quantity of the injection fluid with water to produce a test solution of about 20 µg/mL.

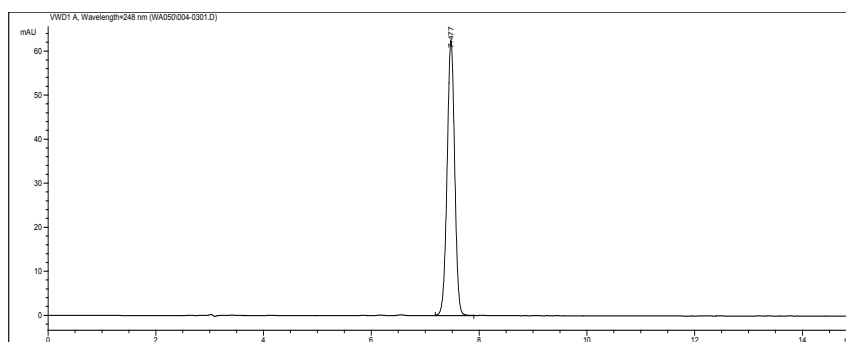
Reference solution: Repeat the procedure using inosine CRS to produce the reference solution.

## Chromatographic conditions

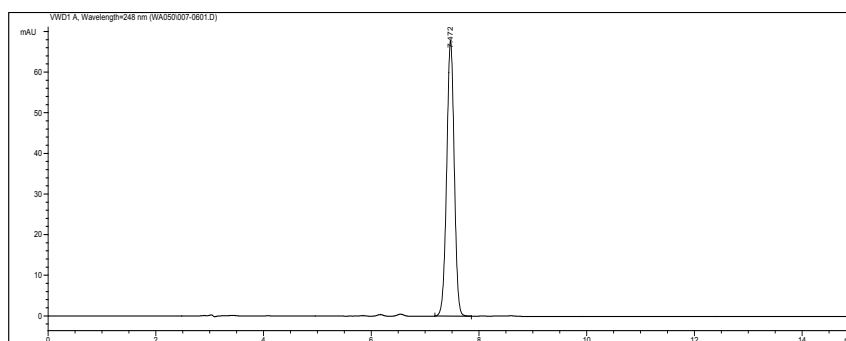
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol = 90:10
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA050\004-0301



The chromatogram of the test solution--- HPLC1\ WA050\007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Inosine	7.47	661.0	14270	/	0.99

# Inosine Injection – 肌昔注射液

Inosine – Method number WA053

## Assay

Test solution: Dilute a quantity of the injection fluid with water to produce a test solution of 0.5 mg/mL.

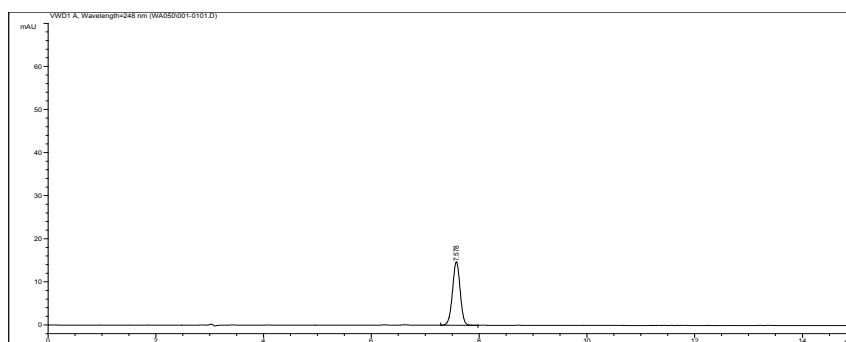
Reference solution: Dilute an accurately measured quantity of the test solution with water to produce a reference solution of 10 µg/mL.

## Chromatographic conditions

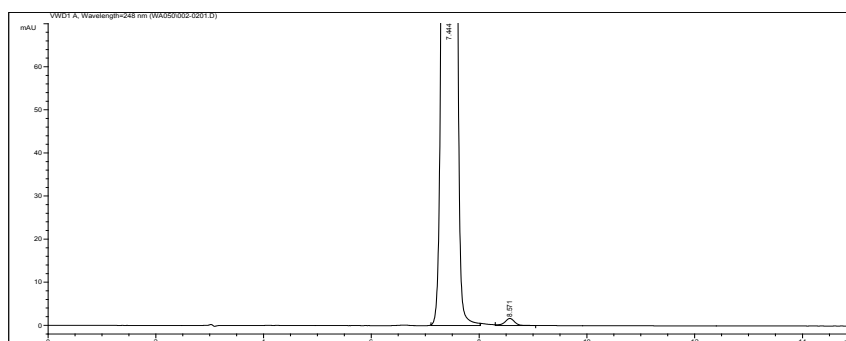
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol = 90:10
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA050\001-0101



The chromatogram of the test solution--- HPLC1\ WA050\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Inosine	7.44	12613.7	13860	/	1.02
Impurity	8.57	21.6	12285	4.0	0.91

# Kitasamycin – 吉他霉素

Kitasamycin (0357-9901) – Method number WA252

## Assay

Test solution: Dissolve an accurately weighed quantity in mobile phase to produce a test solution containing 2 mg/mL.

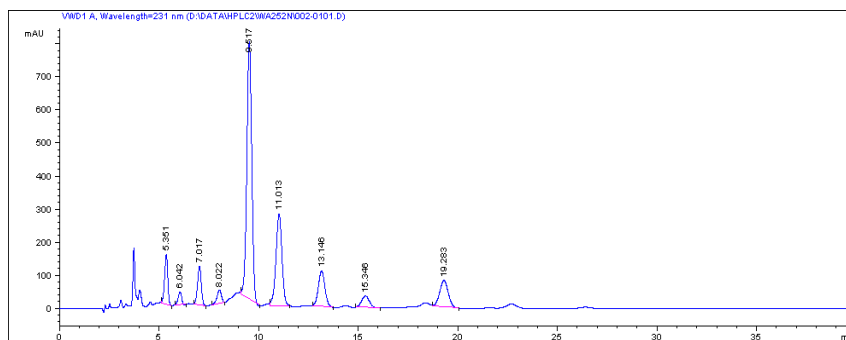
Reference solution: Dissolve a quantity of kitasamycin CRS with mobile phase to produce a reference solution of 0.4 mg/mL.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.1 mol/L ammonium acetate solution: methanol: acetonitrile = 30:65:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 60 °C
- Detector wavelength: 231 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the test solution--- HPLC2WA252N002-0101.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Kitasamycin A9	5.35	1685.0	5392	/	0.86
Kitasamycin A8	6.04	599.0	4983	2.2	0.84
Kitasamycin A7	7.02	1623.4	6410	2.8	0.96
Kitasamycin A6	8.02	624.9	6303	2.7	1.01
Kitasamycin A5	9.52	14116.0	7172	3.5	0.91
Kitasamycin A4	11.01	5838.7	6649	3.0	0.92
Kitasamycin A1	13.15	2535.7	7628	3.7	0.94
Kitasamycin A3	15.35	964.7	7152	3.3	0.96

# Diethylstilbestrol Injection – 己烯雌酚注射液

Diethylstilbestrol (0033-9805) – Method number WA003

## Assay

Test solution: Accurately measure a quantity, equivalent to about 4 mg of diethylstilbestrol, in a 100 mL separation funnel, accurately add 50 mL of methanol, shake vigorously, allow to separate, remove the upper liquid, centrifuge and filter. Dilute the filtrate with methanol to produce a test solution of 80 µg/mL.

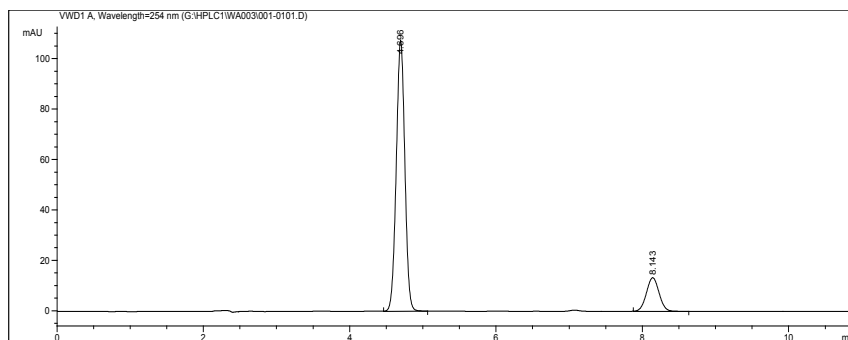
Reference solution: Dissolve an accurately weighed quantity of diethylstilbestrol CRS in methanol and dilute to produce a reference solution of about 80 µg/mL.

## Chromatographic conditions

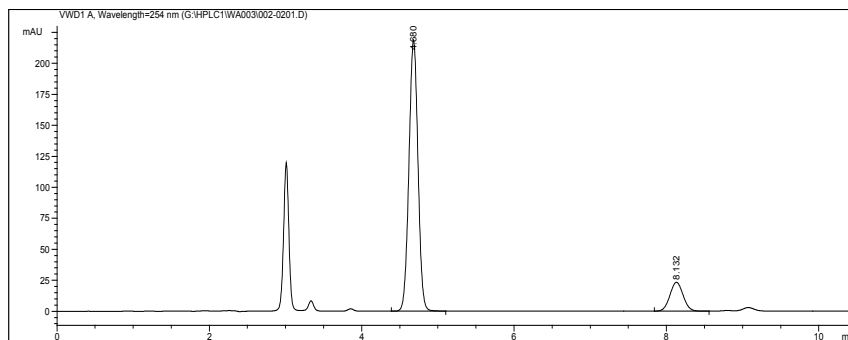
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : water = 75 : 25
- Column temperature: 30 °C
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of chemical reference substance ---HPLC1WA003001-0101



The chromatogram of test solution --- HPLC1WA003002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>i</sub>
Diethylstilbestrol -trans	4.68	1798	7428	/	1.01
Diethylstilbestrol -cis	8.13	280.8	10494	12.89	1.03

# Tolbutamide – 甲苯磺丁脲

Tolbutamide (ARCOS) – Method number WR023

## Assay

Test solution: Accurately weigh about 37.5 mg of the substance in a 25 mL volumetric flask, add 15 mL of methanol, shake to dissolve and dilute to volume with ammonium dihydrogen phosphate BS (pH 3.5), mix well and use as the test solution.

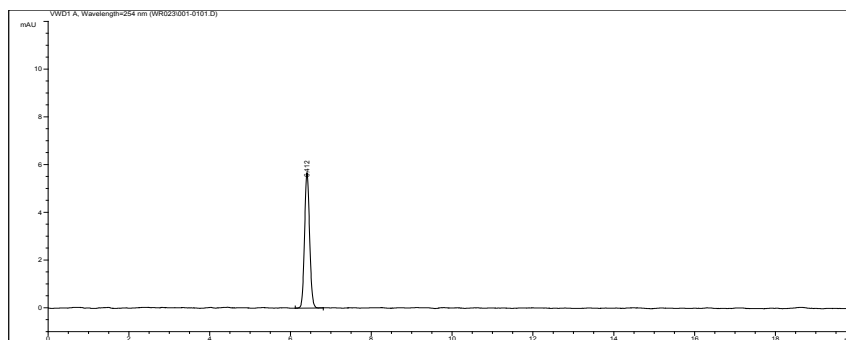
Reference solution: Accurately measure 1 mL of the test solution, dilute with mobile phase to 100 mL, mix well and use as the reference solution.

## Chromatographic conditions

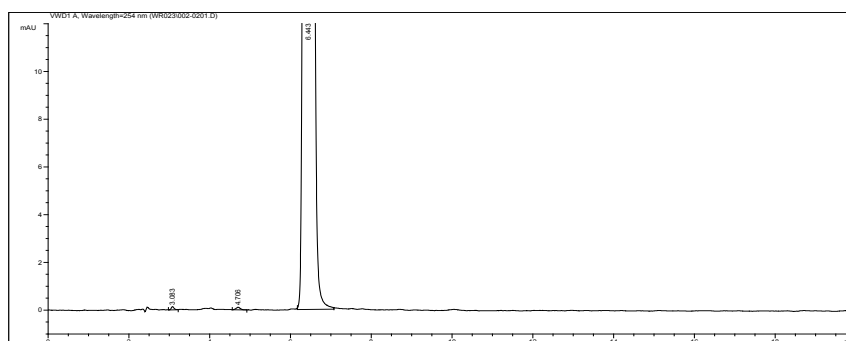
- Column: Agilent ZORBAX SB-C18 4.6x250 mm, 5 µm (880975-902)
- Mobile phase: methanol-ammonium dihydrogen phosphate solution (dissolve 1.725 g of ammonium dehydrate phosphate in 300 mL of water, adjust pH to 3.5±0.05 with phosphoric acid) =625:375
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 40 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WR023\001-0101



The chromatogram of the test solution--- HPLC2\WR023\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tolbutamide	6.44	4554.0	13069	8.6	1.03
Impurity1	3.08	0.6	10621	/	/
Impurity2	4.71	0.7	11013	10.8	1.01

# Mefenamic Acid – 甲芬那酸

Mefenamic Acid (0190-9501) – Method number WR022

## Assay

Test solution: Dissolve a quantity with mobile phase to produce a test solution containing 1 mg/mL.

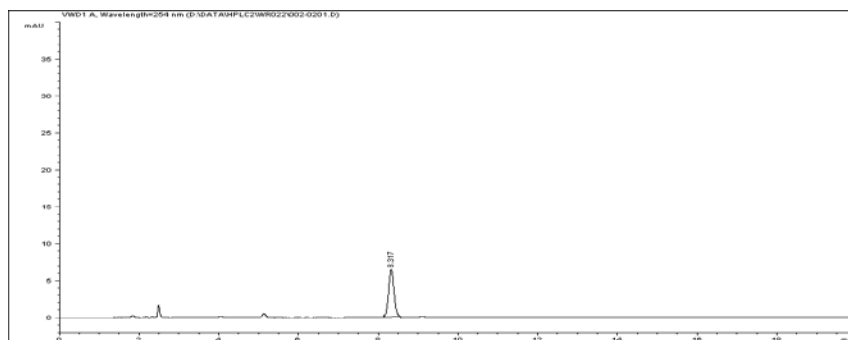
Reference solution: Dissolve a quantity with mobile phase to produce a reference solution containing 5 µg/mL.

## Chromatographic conditions

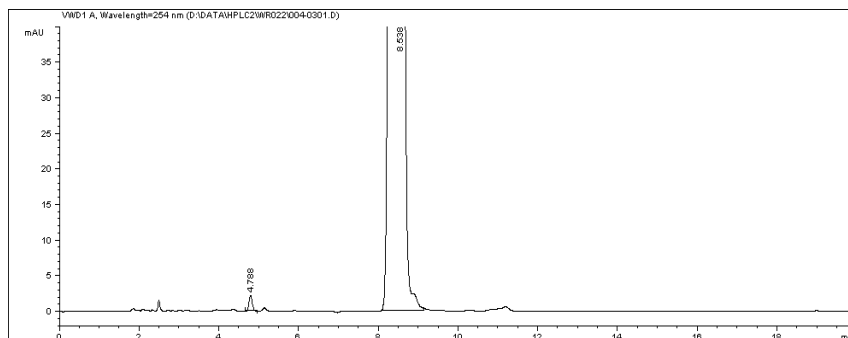
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.05 mol/L ammonium dihydrogen phosphate solution (adjust pH to 5.0 with ammonia TS)-acetonitrile-tetrahydrofuran (40: 46: 14)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR022002-0201.D



The chromatogram of the test solution--- HPLC2WR022004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Mefenamic Acid	8.54	13031.1	9720	15.1	0.71
Impurity	4.79	12.4	16278	/	1.08



# Pefloxacin Mesylate Dihydrate – 甲磺酸培氟沙星

Pefloxacin (130459-200301) – Method number WA028

## Assay

Test solution: Protect from light throughout the procedure. Dissolve a quantity of the substance in water to produce a test solution of 200 µg of pefloxacin per mL.

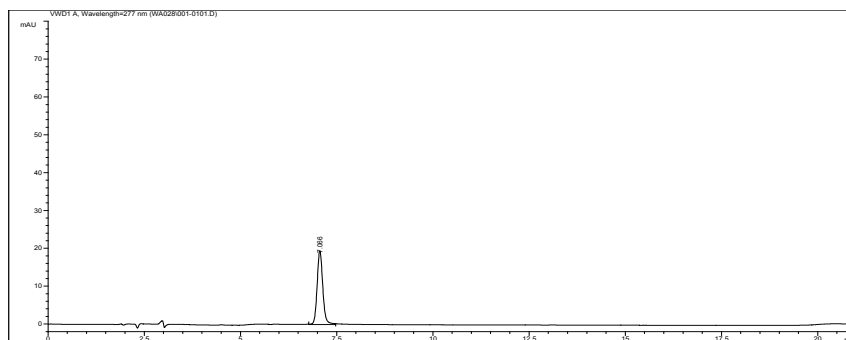
Reference solution: Dilute an accurately measured quantity of test solution with water to produce a reference solution of 2 µg pefloxacin per mL.

## Chromatographic conditions

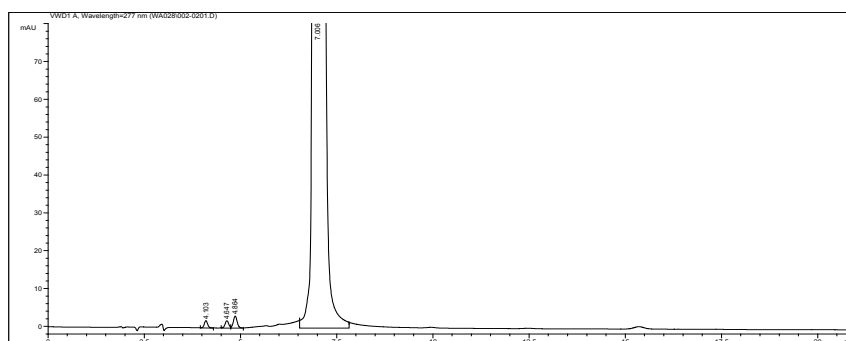
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.04 mol/L potassium dihydrogen phosphate: acetonitrile:0.05 mol/L tetrabutylammonium bromide (adjust pH to 2.5 with phosphoric acid) = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 277 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA028\001-0101



The chromatogram of the test solution--- HPLC1\WA028\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Pefloxacin	7.01	26314.7	7786	/	0.979
Impurity1	4.10	12.0	10968	/	1.05
Impurity2	4.65	12.8	11338	3.3	0.94
Impurity3	4.86	21.8	11926	1.23	1.04

# Pefloxacin Mesylate Capsules – 甲磺酸培氟沙星胶囊

Pefloxacin (130459-200301) – Method number WA031

## Assay

Test solution: Protect from light throughout the procedure. Mix the contents of the capsules, accurately weigh a quantity of the contents, equivalent to about 100 mg of pefloxacin, in a 200 mL volumetric flask, add a quantity of 0.1 mol/L hydrochloride acid to dissolve the pefloxacin, dilute to volume, mix well and filter. Dilute an accurately measured quantity of the filtrate with water to produce a test solution of 20 µg of pefloxacin per mL.

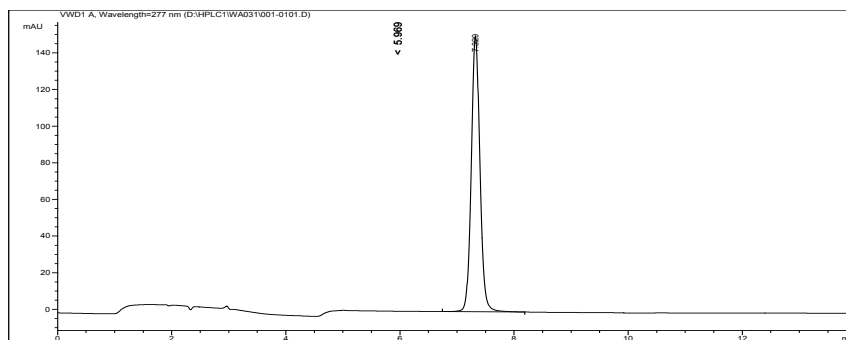
Reference solution: Dissolve an accurately weighed quantity of pefloxacin CRS in water and dilute to produce a reference solution of 20 µg of pefloxacin per mL.

## Chromatographic conditions

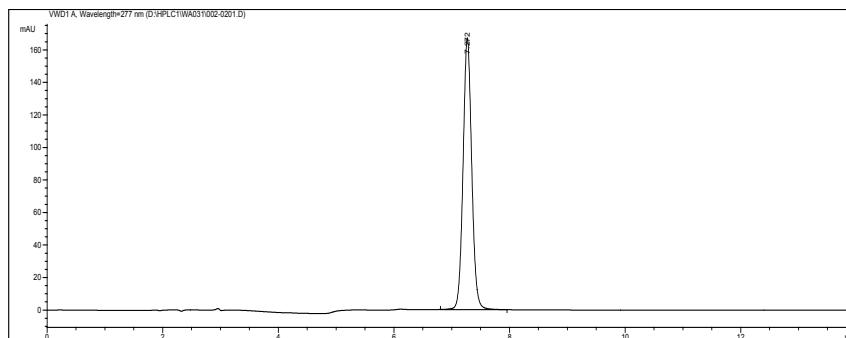
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.04 mol/L potassium dihydrogen phosphate: acetonitrile:0.05 mol/L tetrabutylammonium bromide(adjust pH to 2.5 with phosphoric acid) = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 277 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA031\001-0101



The chromatogram of the test solution--- HPLC1\WA031\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Pefloxacin	7.27	1762.9	11088	/	1.04

# Pefloxacin Mesylate Tablets – 甲磺酸培氟沙星片

Pefloxacin (130459-200301) – Method number WA029

## Assay

Test solution: Protect from light throughout the procedure. Remove the coatings from 20 tablets and grind to a fine powder. Accurately weigh a quantity of powder, equivalent to about 100 mg of pefloxacin, in a 200 mL volumetric flask, add 0.1 mol/L hydrochloride acid and dilute to volume, mix well and filter. Accurately measure a quantity of the filtrate to produce a test solution of 20 µg of pefloxacin per mL.

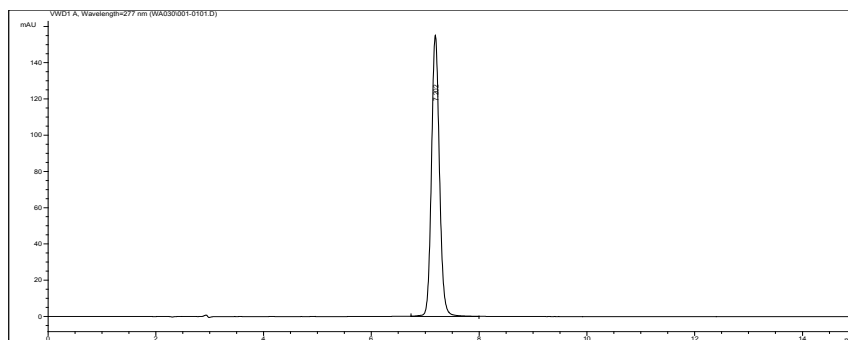
Reference solution: Dissolve an accurately weighed quantity of pefloxacin CRS in water and dilute to produce a reference solution of 20 µg of pefloxacin per mL.

## Chromatographic conditions

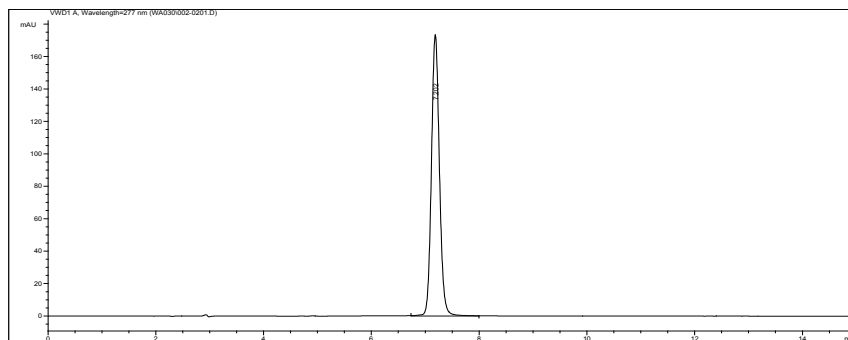
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.04 mol/L potassium dihydrogen phosphate: acetonitrile: 0.05 mol/L tetrabutylammonium bromide (adjust pH to 2.5 with phosphoric acid) = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 277 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA030001-0101



The chromatogram of the test solution--- HPLC1WA030002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Pefloxacin	7.19	1789.4	10842	/	1.06

# Pefloxacin Mesylate Injection – 甲磺酸培氟沙星注射液

Pefloxacin (130459-200301) – Method number WA030

## Assay

Test solution: Protect from light throughout the procedure. Dilute an accurately measured quantity of the injection fluid with water to produce a test solution of 20 µg of pefloxacin per mL.

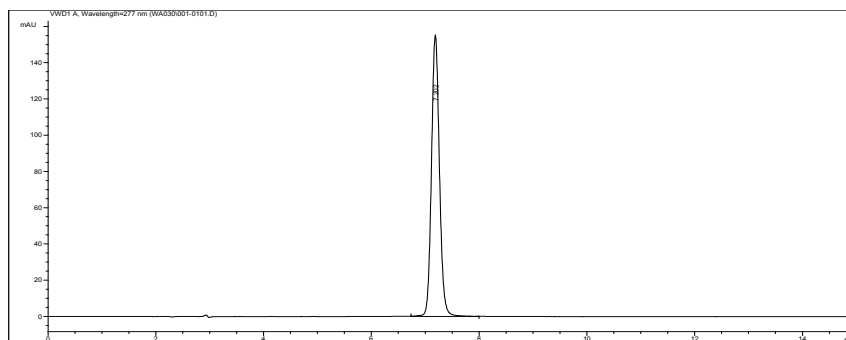
Reference solution: Repeat the procedure using an accurately weighed quantity of pefloxacin CRS to produce the reference solution.

## Chromatographic conditions

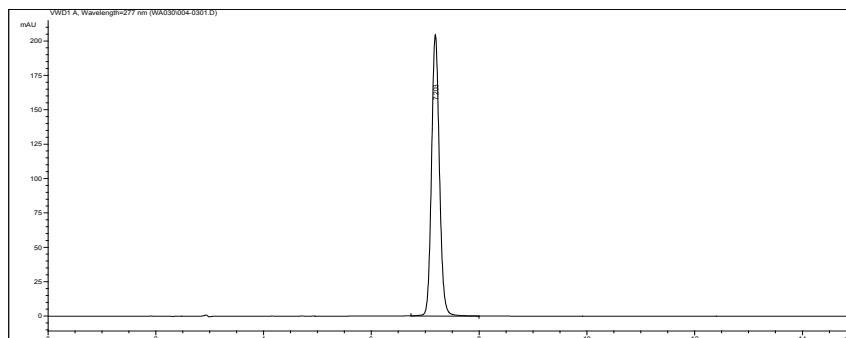
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.04 mol/L potassium dihydrogen phosphate: acetonitrile:0.05 mol/L tetrabutylammonium bromide (adjust pH to 2.5 with phosphoric acid) = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 277 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA030\001-0101



The chromatogram of the test solution--- HPLC1\WA030\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Pefloxacin	7.19	2088.7	11175	/	1.06

# Metronidazole – 甲硝唑

Metronidazole (100191-200305) 2-methyl-5-nitroimidazole (ARCOS) – Method number WA021

## Assay

**Test solution:** Accurately weigh about 100 mg, dissolve in methanol, dilute to 100 ml and mix well. Accurately measure a quantity, dilute with mobile phase to produce a test solution of 0.1 mg/mL.

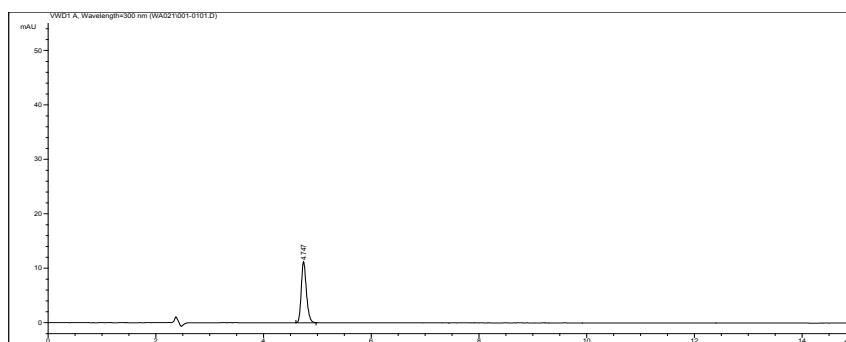
**Reference solution:** Dissolve an accurately weigh quantity of about 25 mg of 2-methyl-5-nitroimidazole CRS in methanol, dilute to 100 mL and mix well. Accurately measure a quantity and dilute with mobile phase to produce a reference solution of 1 µg/mL.

## Chromatographic conditions

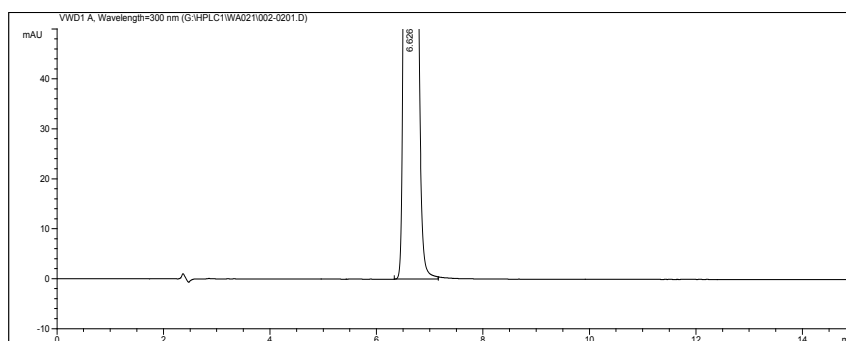
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : water = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 300 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA021\001-0101



The chromatogram of the test solution --- HPLC2WA021\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
2-Methyl-5-Nitroimidazole	4.75	/	/	/	/
Metronidazole	6.63	6715.1	10423	/	1.14

# Metronidazole Capsules – 甲硝唑胶囊

## 2-methyl-5-nitroimidazole (ARCOS) – Method number WA026

### Assay

**Test solution:** Grind the contents to a fine powder and mix well. Accurately weigh quantity of the powder, equivalent to about 0.2g metronidazole, in a 100 mL volumetric flask, add a quantity water, shake to dissolve the metronidazole, dilute with water to volume and shake well. Filter and transfer 5 mL of filtrate in a 100 mL volumetric flask, dilute with water, shake well and use as the test solution.

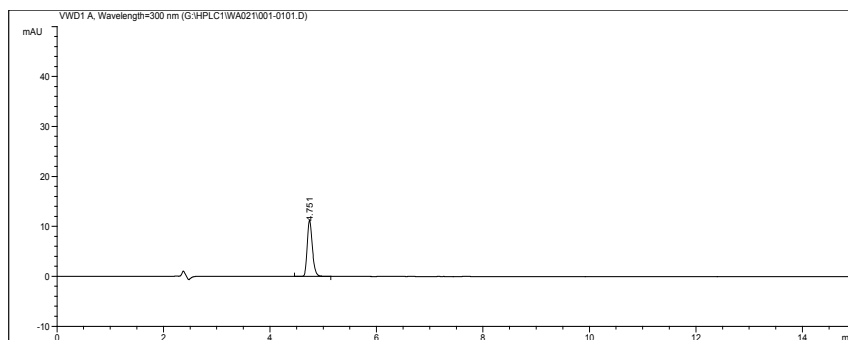
**Reference solution:** Dissolve an accurately weighed quantity of about 25 mg of 2-methyl-5-nitroimidazole in methanol, dilute to 100 mL and mix well. Accurately measure a quantity and dilute with water to produce a reference solution of 1 µg/mL.

### Chromatographic conditions

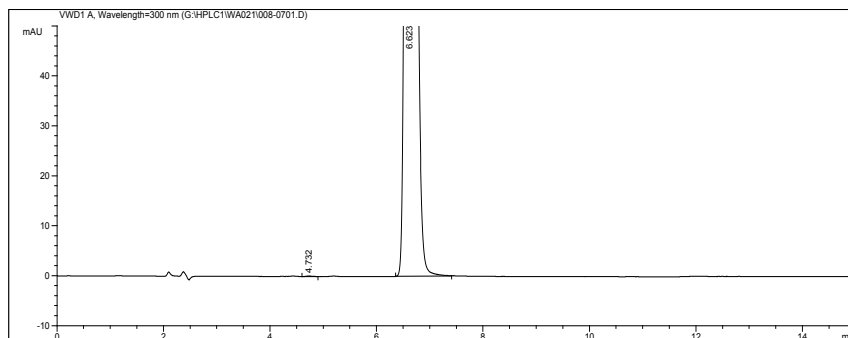
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:water = 20:80
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 300 nm
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA021001-0101



The chromatogram of the test solution--- HPLC1WA021008-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
2-Methyl-5-nitroimidazole	4.73	0.7	13712	/	1.51
Metronidazole	6.63	5620.2	11126	9.0	1.16

# Metronidazole Tablets – 甲硝唑片

2-methyl-5-nitroimidazole (ARCOS) – Method number WA022

## Assay

**Test solution:** Accurately weigh a quantity of powder, equivalent to about 0.2 g of metronidazole, in a 100 mL volumetric flask, add a quantity of water, shake to dissolve the metronidazole, dilute with water to volume and mix well. Filter and accurately transfer 5 mL of the filtrate to a 100 mL volumetric flask, dilute with water, mix well and use as the test solution.

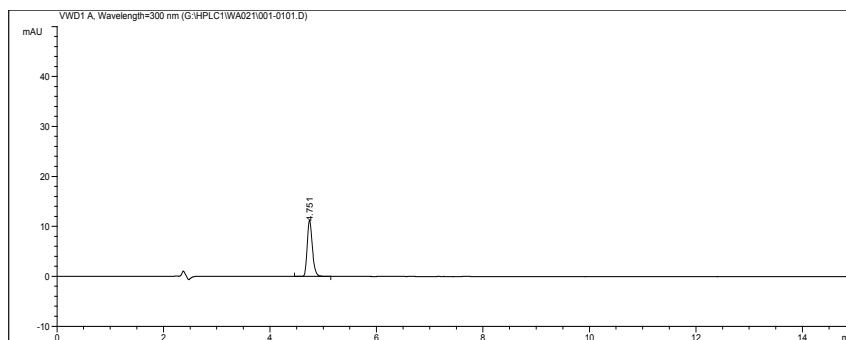
**Reference solution:** Dissolve an accurately weighed quantity of about 25 mg of 2-methyl-5-nitroimidazole in methanol, dilute to 100 mL and mix well. Accurately measure a quantity and dilute with water to produce a reference solution of 1 µg/mL.

## Chromatographic conditions

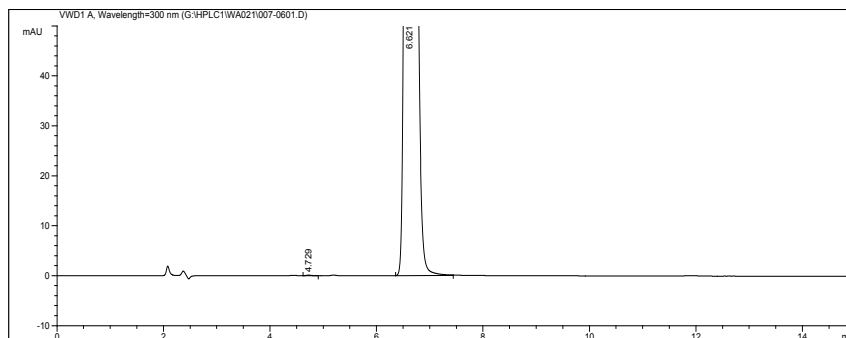
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : water = 20:80
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 300 nm
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA021\001-0101



The chromatogram of the test solution --- HPLC1\WA021\007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
2-Methyl-5-Nitroimidazole	4.73	0.8	13151	/	1.00
Metronidazole	6.63	5656.6	10431	8.95	1.15

# Metronidazole and Glucose Injection – 甲硝唑葡萄糖注射液

## 2-methyl-5-nitroimidazole (ARCOS) – Method number WA027

### Assay

**Test solution:** Dilute a quantity with water to produce a test solution containing 0.1 mg of metronidazole per mL.

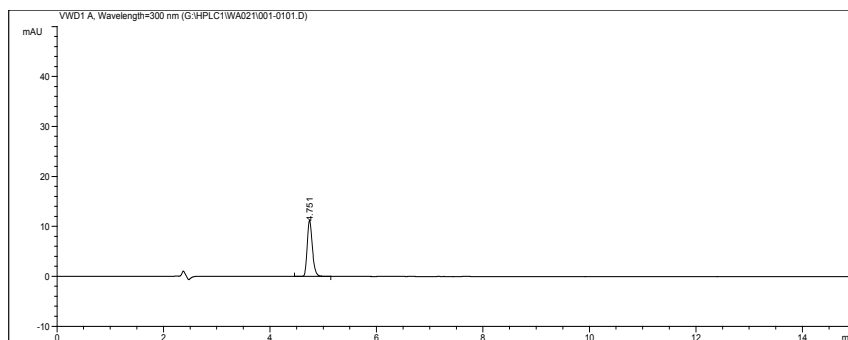
**Reference solution:** Dissolve an accurately weighed quantity of about 25 mg of 2-methyl-5-nitroimidazole in methanol, dilute to 100 mL and mix well. Accurately measure a quantity and dilute with water to produce a reference solution of 1 µg/mL.

### Chromatographic conditions

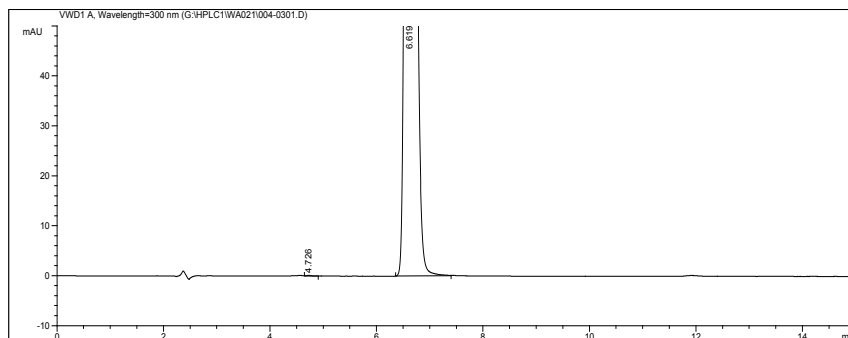
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol:water = 20:80
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 300 nm
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA021001-0101



The chromatogram of the test solution--- HPLC1WA021004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
2-Methyl-5-Nitroimidazole	4.73	0.8	11058	/	1.32
Metronidazole	6.63	5055.1	11115	8.8	1.16



# Metronidazole Suppositories – 甲硝唑栓

## 2-methyl-5-nitroimidazole (ARCOS) – Method number WA025

### Assay

**Test solution:** Accurately weigh 10 suppositories and cut into pieces. Dissolve an accurately weighed quantity, equivalent to about 0.1g of metronidazole, with a quantity of mobile phase in 100 mL volumetric flask on a water bath of 70 °C, shake to dissolve the metronidazole. Allow to cool, dilute with mobile phase and mix well. Put in an ice bath for 1.5 hours, filter and transfer 5 mL of the filtrate to a 50 mL volumetric flask. Dilute with water to volume, mix well and use as the test solution.

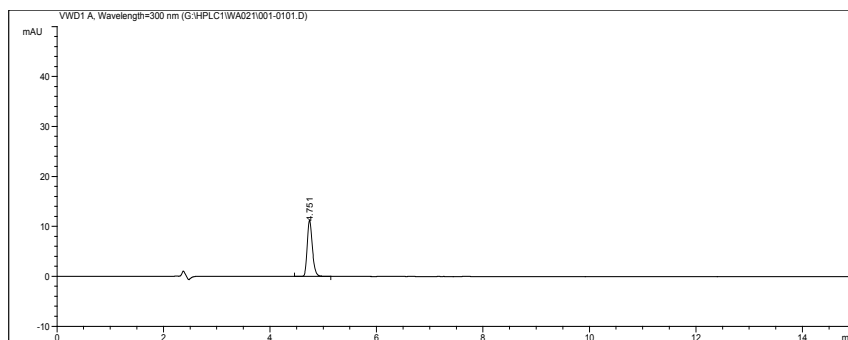
**Reference solution:** Dissolve an accurately weighed quantity of about 25 mg of 2-methyl-5-nitroimidazole in methanol, dilute to 100 mL and mix well. Accurately measure a quantity and dilute with water to produce a reference solution of 1 µg/mL.

### Chromatographic conditions

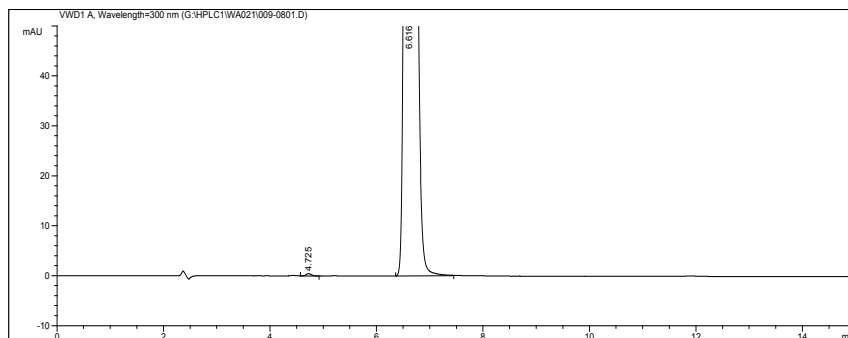
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : water = 20:80
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 300 nm
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA021001-0101



The chromatogram of the test solution--- HPLC1WA021009-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
2-Methyl-5-Nitroimidazole	4.73	3.2	12193	/	1.10
Metronidazole	6.63	5925.5	11106	9.0	1.15

# Metronidazole Vaginal Effervescent Tablets – 甲硝唑阴道泡腾片

## 2-methyl-5-nitroimidazole (ARCOS) – Method number WA023

### Assay

**Test solution:** Accurately weigh a quantity of powder, equivalent to about 0.2 g of metronidazole, in a 100 mL volumetric flask, add a quantity of water and shake to dissolve the metronidazole, dilute with water to volume and mix well. Filter and accurately transfer 5 mL of the filtrate to a 100 mL volumetric flask, dilute with water, mix well and use as the test solution.

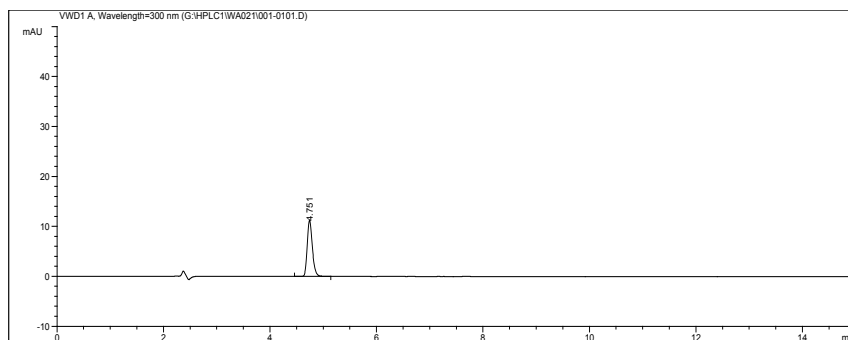
**Reference solution:** Dissolve an accurately weighed quantity of about 25 mg of 2-methyl-5-nitroimidazole in methanol, dilute to 100 mL and mix well. Accurately measure a quantity and dilute with water to produce a reference solution of 1 µg/mL.

### Chromatographic conditions

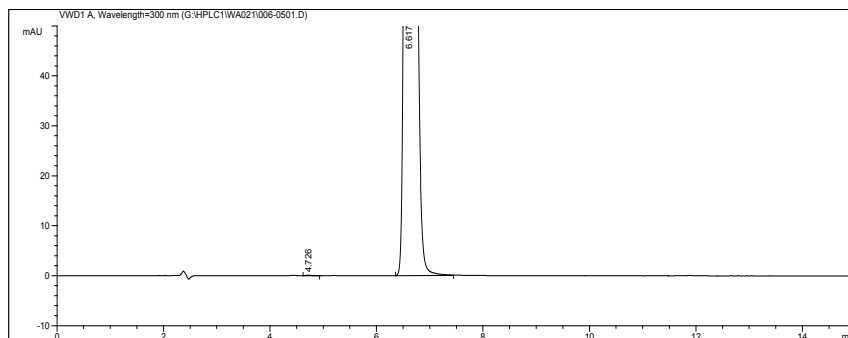
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : water = 20:80
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 300 nm
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1WA021001-0101



The chromatogram of the test solution--- HPLC2WA021006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
2-Methyl-5-Nitroimidazole	4.73	0.7	13814	/	1.15
Metronidazole	6.63	5537.5	10419	9.0	1.14

# Metronidazole Injection – 甲硝唑注射液

## 2-methyl-5-nitroimidazole (ARCOS) – Method number WA024

### Assay

**Test solution:** Dilute a quantity with water to produce a test solution containing 0.1 mg of metronidazole per mL.

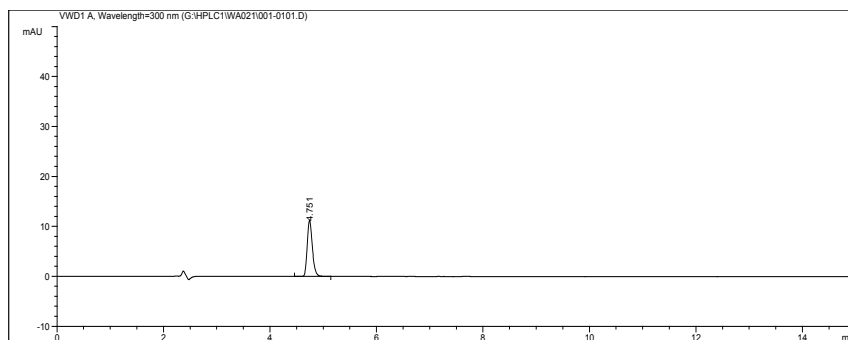
**Reference solution:** Dissolve an accurately weighed quantity of about 25 mg of 2-methyl-5-nitroimidazole in methanol, dilute to 100 mL and mix well. Accurately measure a quantity and dilute with water to produce a reference solution of 1 µg/mL.

### Chromatographic conditions

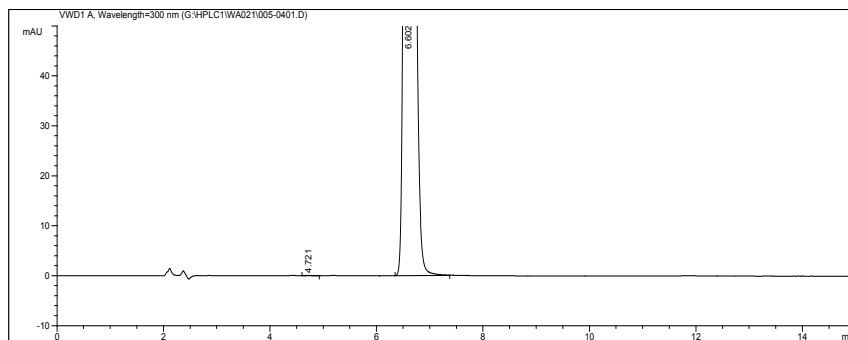
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : water = 20:80
- Flow rate: 1.0 mL/min
- Column temperature: 30 °C
- Detector wavelength: 300 nm
- Injection volume: 10 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA021001-0101



The chromatogram of the test solution--- HPLC1\WA021005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
2-Methyl-5-Nitroimidazole	4.72	0.5	13440	/	1.19
Metronidazole	6.62	4557.5	10711	9.0	1.15

# Vinorelbine Tartrate – 酒石酸长春瑞滨

## Vinorelbine tartrate (ACROS) – Method number WA187

### Assay

Test solution: Dissolve a quantity of the substance in mobile phase to produce a test solution of 1.4 mg/mL.

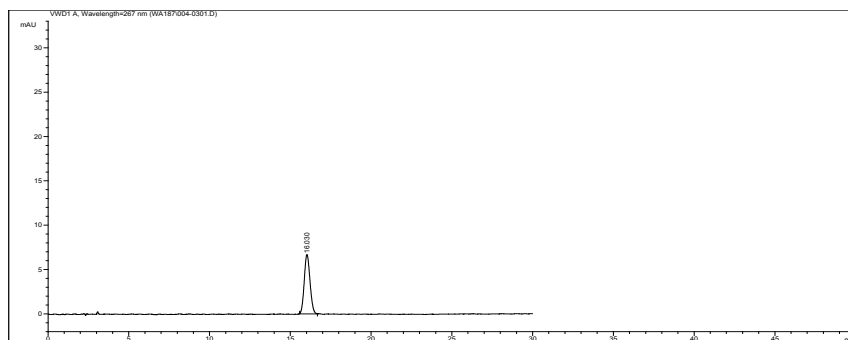
Reference solution: Accurately measure a quantity of the test solution and dilute with mobile phase to produce a reference solution of 14 µg/mL.

### Chromatographic conditions

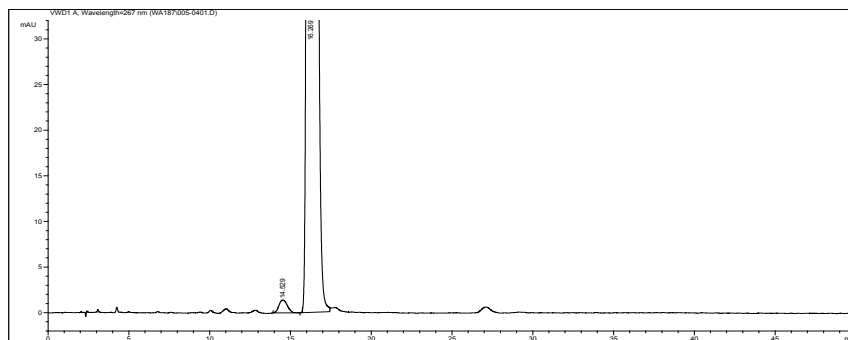
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.05M sodium dihydrogen phosphate solution (adjust to pH 4.2 with phosphoric acid) : 0.2 % sodium decyl-sulfonate solution in methanol =33:67
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 40 °C
- Detector wavelength: 267 nm

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA187\004-0301



The chromatogram of the test solution--- HPLC2\ WA187\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vinorelbine Tartrate	16.29	15465.7	8643	2.1	1.20
Degrading product	14.53	51.1	3506	/	1.13

# Vinorelbine Tartrate Injection – 酒石酸长春瑞滨注射液

Vinorelbine tartrate (ACROS) – Method number WA188

## Assay

Test solution: Accurately measure a quantity of the injection fluid and dilute with water to produce a test solution of 0.1 mg of vinorelbine per mL, which is equivalent to about 0.14 mg of vinorelbine tartrate.

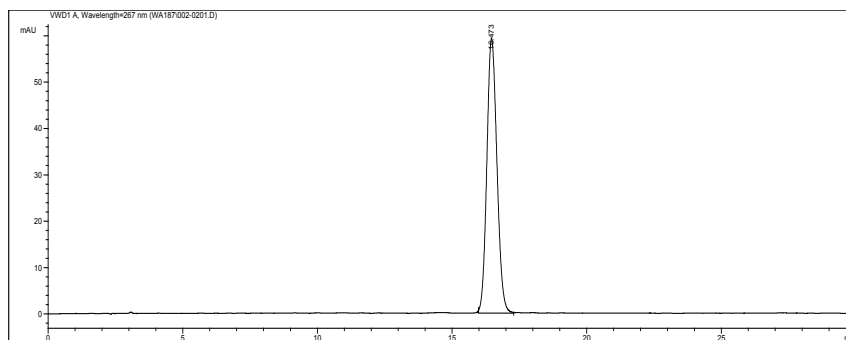
Reference solution: Repeat the procedure using vinorelbine tartrate CRS to produce the reference solution.

## Chromatographic conditions

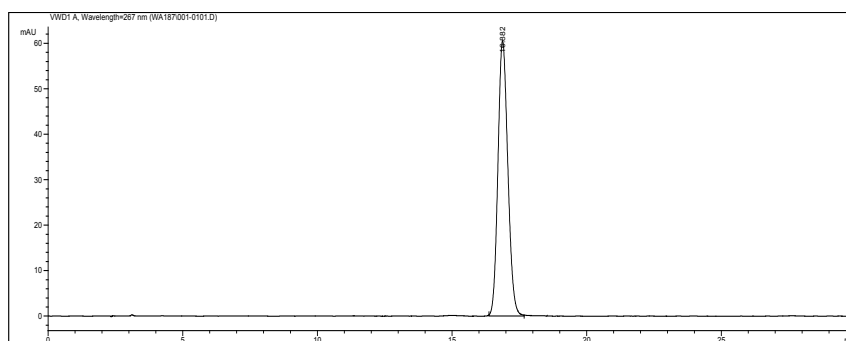
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.05 M sodium dihydrogen phosphate solution (adjust to pH 4.2 with phosphoric acid) : 0.2 % sodium decyl-sulfonate solution in methanol = 33:67
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 40 °C
- Detector wavelength: 267 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA187\001-0101



The chromatogram of the test solution--- HPLC2\ WA187\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Vinorelbine Tartrate	16.88	1543.1	9273	/	1.09

# Codeine Phosphate and Platycodon Tablets – 可待因桔梗片

Codeine phosphate (171203-200303) – Method number WA241

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 12 mg of codeine phosphate, in a 50 mL volumetric flask, add 2.5 mL of water and treat ultrasonically until dissolved. Add a quantity of methanol, treat ultrasonically for 10 minutes to dissolve the codeine phosphate, allow to cool, dilute with methanol to volume, shake thoroughly and filter. Accurately measure 2 mL of the filtrate in a 10 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

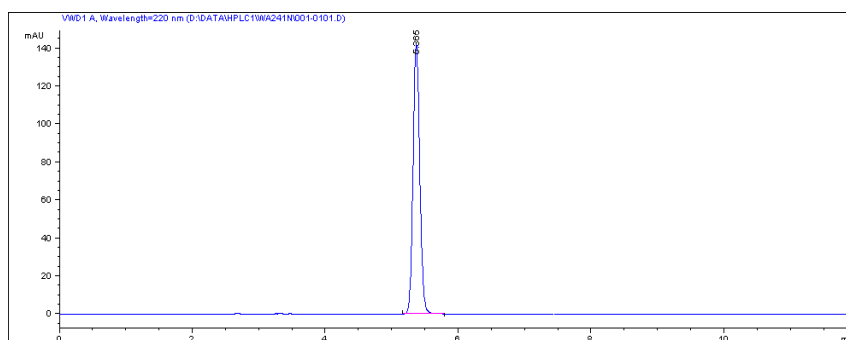
Reference solution: Dissolve an accurately weighed quantity of codeine phosphate CRS in mobile phase to produce a reference solution of about 48 µg/mL.

## Chromatographic conditions

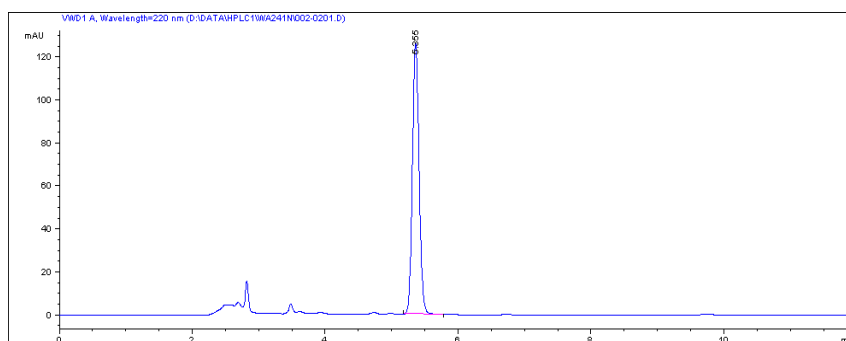
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile : 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 3.0 with phosphoric acid) = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA241N001-0101



The chromatogram of the test solution--- HPLC1\WA241N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Codeine Phosphate	5.36	888.8	13537	/	1.06

# Clarithromycin – 克拉霉素

Clarithromycin (30356-200403) – Method number WR157

## Assay

Test solution: Dissolve an accurately weighed quantity in mobile phase to produce a test solution of about 1 mg/mL.

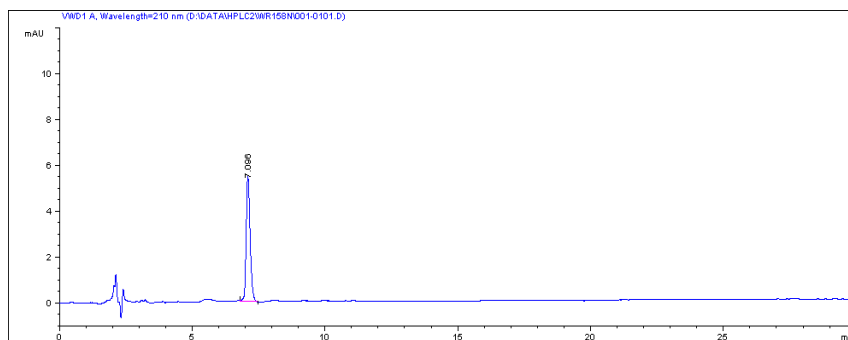
Reference solution: Accurately measure 5 mL of the test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

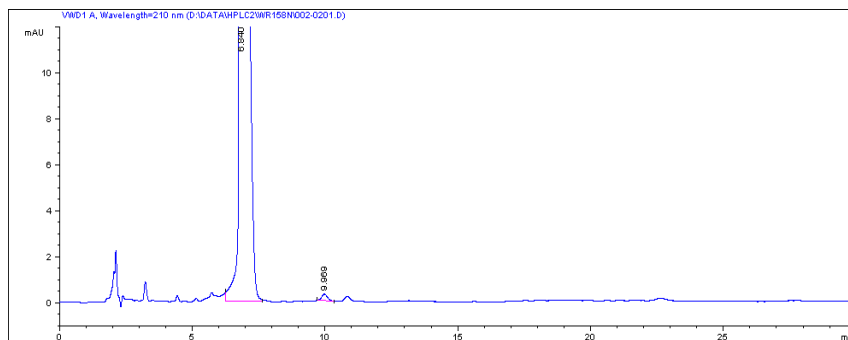
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: phosphate BS (dissolve 9.11 g of potassium dihydrogen phosphate in water and dilute to 1000 mL, add 2 mL of triethylamine, adjust pH to 5.5 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 45 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WR158N001-0101



The chromatogram of the test solution --- HPLC2WR158N002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clarithromycin	6.84	1130.7	3774	/	/
Impurity	9.97	4.7	10146	7.4	0.99

# Clarithromycin Capsules – 克拉霉素胶囊

Clarithromycin (30356-200403) – Method number WR159

## Assay

Test solution: Dissolve an accurately weighed quantity of the contents of the capsules in mobile phase and dilute to produce a solution of 0.35 mg/mL. Filter and use the filtrate as the test solution.

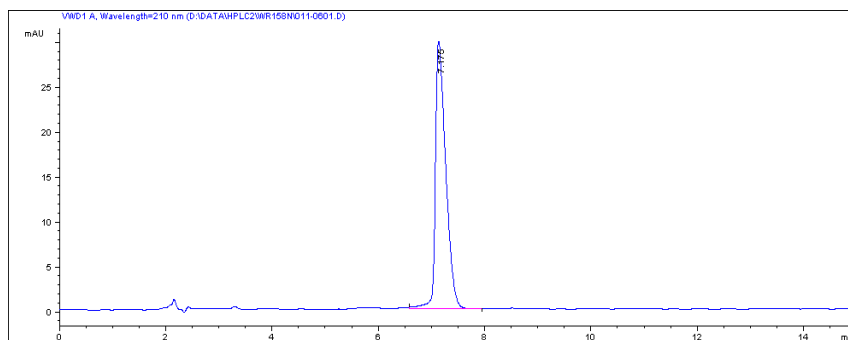
Reference solution: Repeat the operation using clarithromycin CRS to produce the reference solution.

## Chromatographic conditions

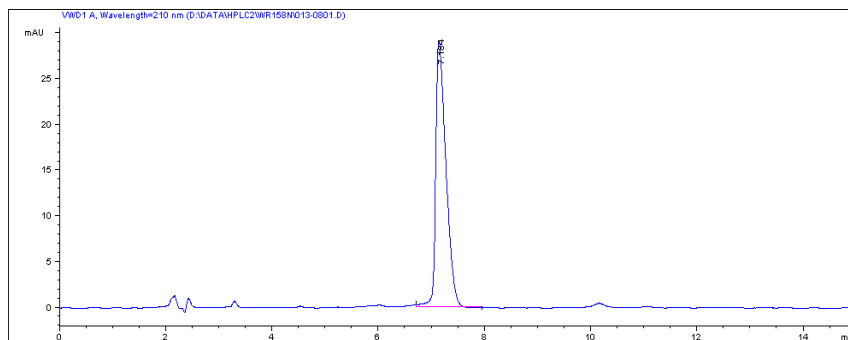
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: phosphate BS (dissolve 9.11 g of potassium dihydrogen phosphate in water and dilute to 1000 mL, add 2 mL of triethylamine, adjust pH to 5.5 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 45 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR158N011-0601



The chromatogram of the test solution--- HPLC2WR158N013-0801

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clarithromycin	7.18	392.0	6130	/	1.30



# Clarithromycin Capsules – 克拉霉素胶囊

Clarithromycin (30356-200403) – Method number WR159

## Assay

Test solution: Dissolve an accurately weighed quantity of the contents of the capsules in mobile phase and dilute to produce a solution of 1 mg/mL. Filter and use the filtrate as the test solution.

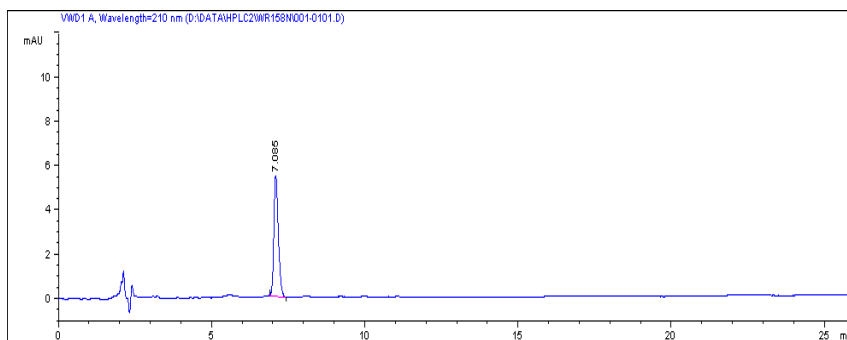
Reference solution: Accurately measure 0.5 mL of the test solution in a 10 ml volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

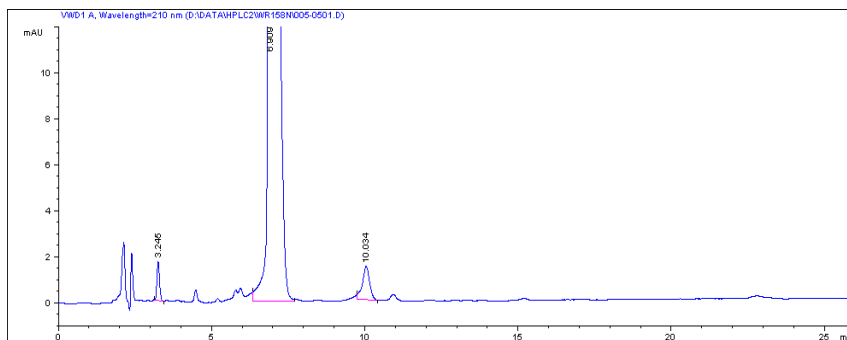
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile:phosphate BS (dissolve 9.11 g of potassium dihydrogen phosphate in water and dilute to 1000 mL, add 2 mL of triethylamine, adjust pH to 5.5 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 45 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR158N001-0101



The chromatogram of the test solution--- HPLC2WR158N005-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Impurity1	3.25	7250	6984	/	1.11
Clarithromycin	6.92	1091.1	3864	12.3	/
Impurity2	10.03	24.5	9863	7.3	0.94

# Clarithromycin Granules – 克拉霉素颗粒

Clarithromycin (30356-200403) – Method number WA255

## Assay

Test solution: Grind to a fine powder, accurately weigh a quantity of the powder, equivalent to about 0.35 mg of clarithromycin, in a 1 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

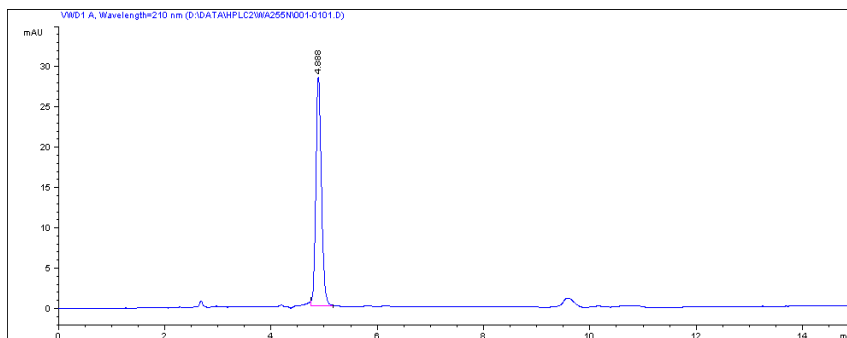
Reference solution: Repeat the procedure using clarithromycin CRS to produce the reference solution.

## Chromatographic conditions

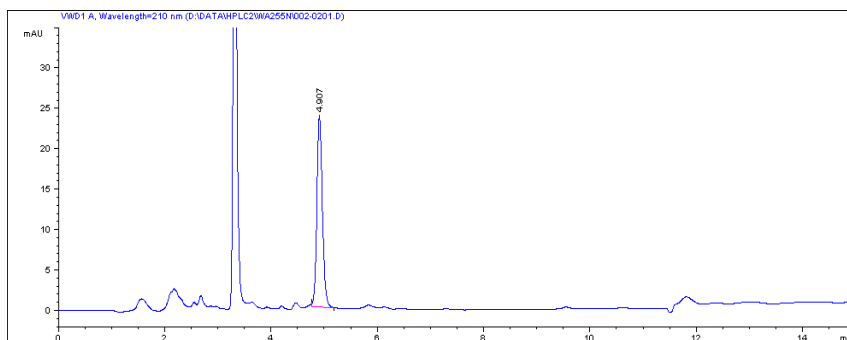
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetonitrile: phosphate BS (dissolve 9.11 g potassium dihydrogen phosphate in water, and dilute with water to 1000 mL, add 2 mL of triethylamine, adjust pH to 5.5 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 45 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA255\N001-0101



The chromatogram of the test solution --- HPLC2\WA255\N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clarithromycin	4.91	174.7	11034	/	1.10

# Clarithromycin Tablets – 克拉霉素片

Clarithromycin (30356-200403) – Method number WR158

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase and dilute to produce a solution of 0.35 mg/mL. Filter and use the filtrate as the test solution.

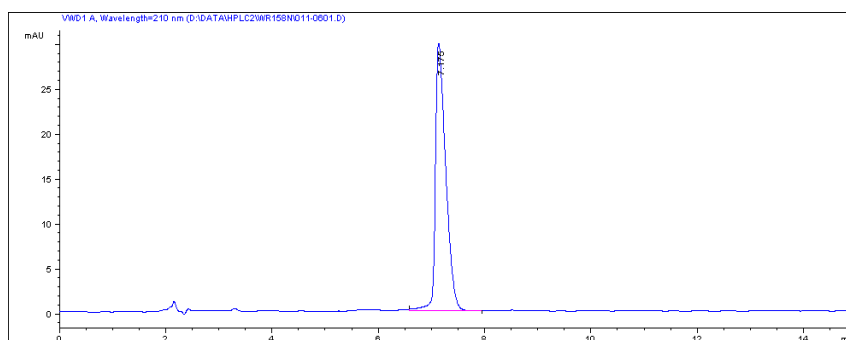
Reference solution: Repeat the procedure using clarithromycin CRS to produce the reference solution.

## Chromatographic conditions

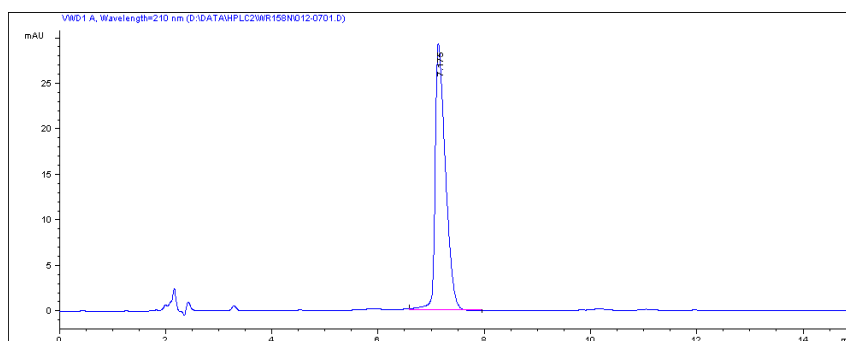
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: phosphate BS(dissolve 9.11 g of potassium dihydrogen phosphate in water and dilute to 1000 mL, add 2 mL of triethylamine, adjust pH to 5.5 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 45 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WR158N011-0601



The chromatogram of the test solution --- HPLC2WR158N012-0701

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clarithromycin	7.17	396.1	5721	/	1.30

# Clarithromycin Tablets – 克拉霉素片

Clarithromycin (30356-200403) – Method number WR158

## Assay

Test solution: Grind the tablets to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase and dilute to produce a solution of 1 mg/mL. Filter and use the filtrate as the test solution.

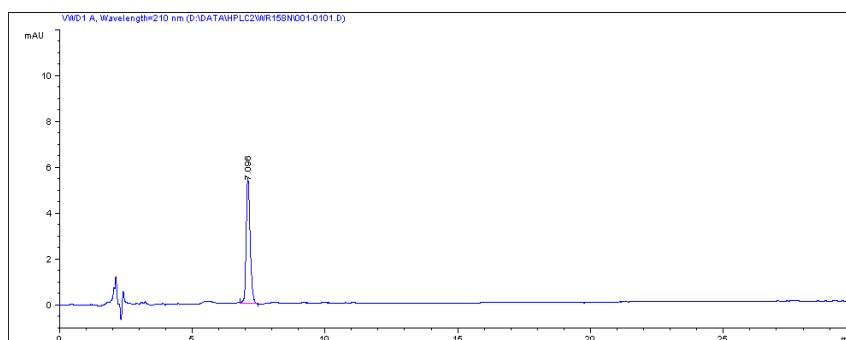
Reference solution: Accurately measure 0.5 mL of the test solution in a 10 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

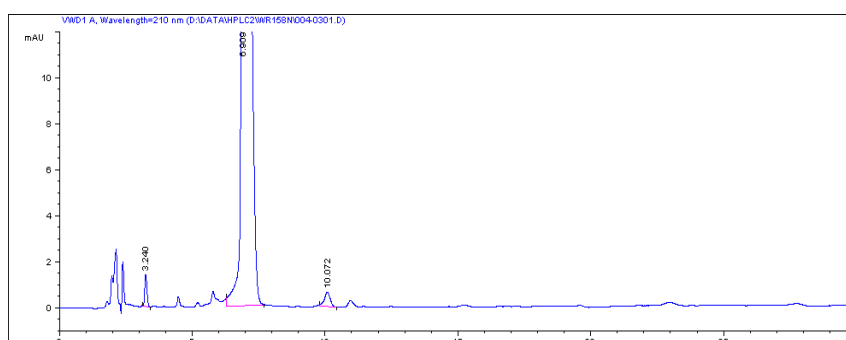
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: phosphate BS(dissolve 9.11 g of potassium dihydrogen phosphate in water and dilute to 1000 mL, add 2 mL of triethylamine, adjust pH to 5.5 with phosphoric acid) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 45 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR158N001-0101



The chromatogram of the test solution--- HPLC2WR158N004-0301

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	3.24	8.4	6984	/	1.13
Clarithromycin	6.91	1136.4	3779	12.1	/
Impurity2	10.07	9.7	10800	7.5	0.93

# Clotrimazole Oral Pellices – 克霉唑口腔药膜

Clotrimazole (100037-200306) – Method number WR160

## Assay

**Test solution:** Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 12.5 mg of clotrimazole, in a 25 mL volumetric flask, add a quantity of methanol, treat ultrasonically for 10 minutes until the clotrimazole dissolves, allow to cool to room temperature, dilute with methanol to volume, shake well, filter and use the filtrate as the test solution.

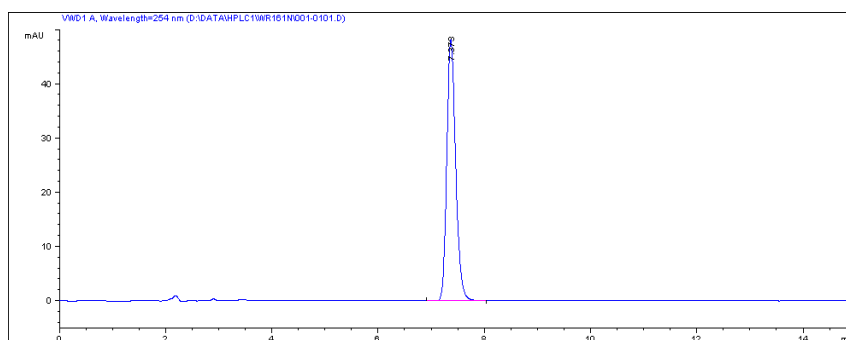
**Reference solution:** Repeat the procedure using clotrimazole CRS to produce the reference solution.

## Chromatographic conditions

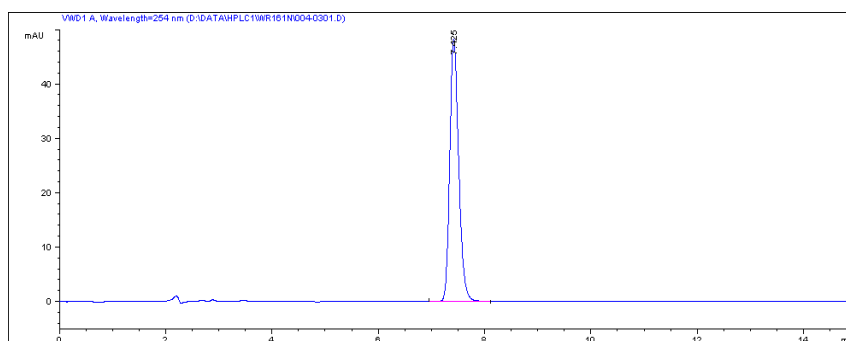
- Column: Agilent ZORBAX Extend C18 4.6×250 mm, 5 µm (770450-902)
- Mobile phase: phosphate solution (dissolve 4.35 g of dipotassium hydrogen phosphate, dilute to 1000 mL with water):methanol = 20:80
- Flow rate: 1.0 mL/min Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR160\N001-0101



The chromatogram of the test solution --- HPLC1\WR160\N004-0301

Constituents (reference solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clotrimazole	7.43	566.3	9221	/	1.15

# Clotrimazole Solution – 克霉唑溶液

Clotrimazole (100037-200306) – Method number WR161

## Assay

Test solution: Accurately measure 2 mL of the solution in a 50 mL volumetric flask and dilute with methanol to volume, shake well and use as the test solution.

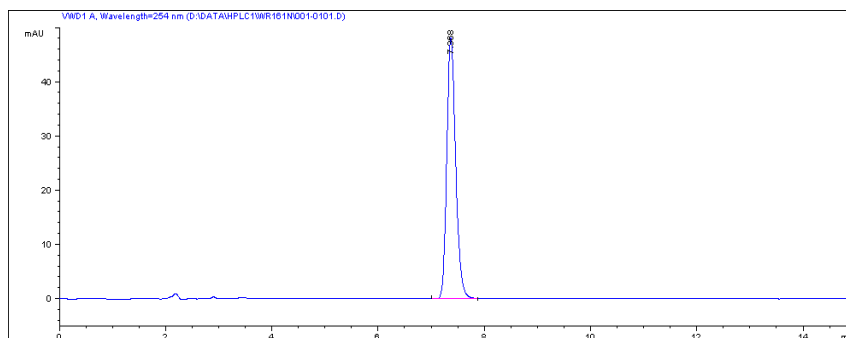
Reference solution: Dissolve an accurately weighed quantity of clotrimazole CRS in methanol to produce a reference solution of 0.6 mg/mL.

## Chromatographic conditions

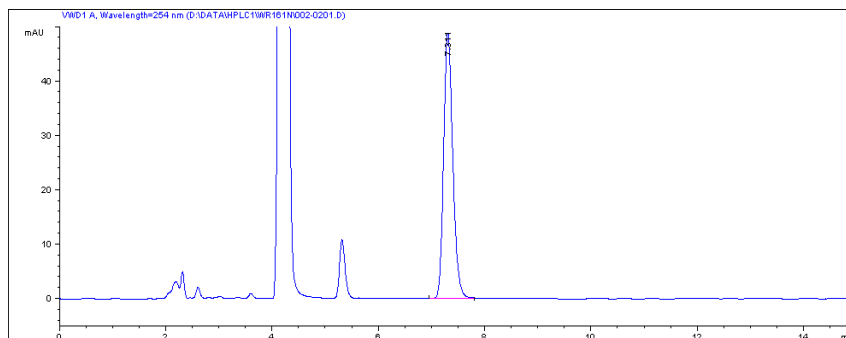
- Column: Agilent ZORBAX Extend C18 4.6×250 mm, 5 µm (770450-902)
- Mobile phase: phosphate solution (dissolve 4.35 g of dipotassium hydrogen phosphate, dilute to 1000 mL with water):methanol = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR161\N001-0101



The chromatogram of the test solution --- HPLC1\WR161\N002-0201

Constituents (reference solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clotrimazole	7.31	586.4	7671	/	1/13

# Clotrimazole Ointment – 克霉唑软膏

Clotrimazole (100037-200306) – Method number WA058

## Assay

Test solution: Mix the cream well. Accurately weigh a quantity of the cream, equivalent to about 12.5 mg of clotrimazole, into a 25 mL volumetric flask, add a quantity of methanol, heat on a water bath at 50 °C, shake until the clotrimazole dissolves, allow to cool to room temperature, dilute with methanol to volume, shake well, put in an ice-water bath for 2 hours, filter immediately, allow to reach room temperature and use the filtrate as the test solution.

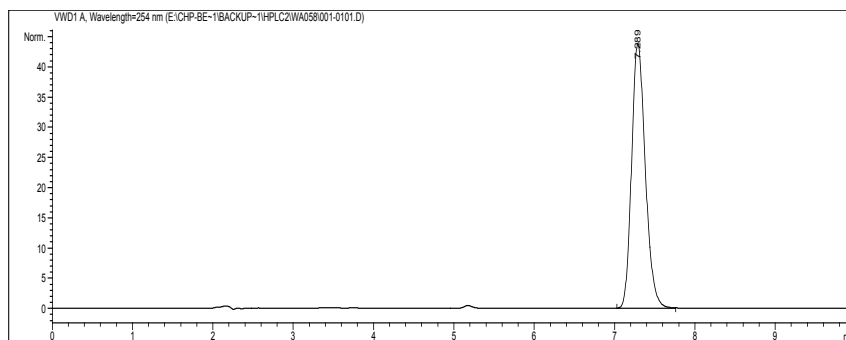
Reference solution: Repeat the procedure using clotrimazole CRS to produce the reference solution.

## Chromatographic conditions

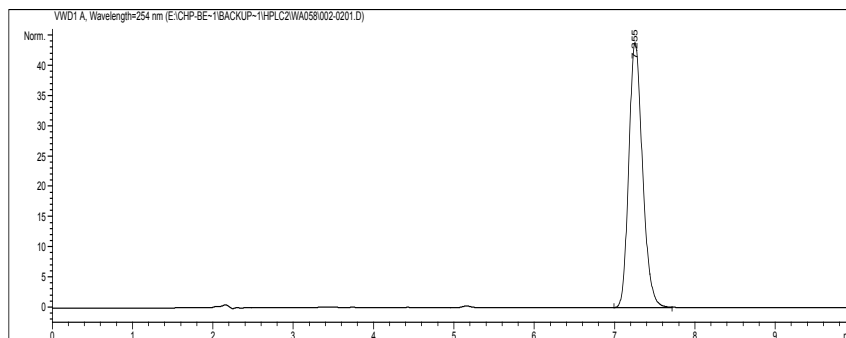
- Column : Agilent ZORBAX Extend-C18 4.6×250 mm, 5 µm (770450-902)
- Mobile phase: phosphate solution (dissolve 4.35 g dipotassium hydrogen phosphate and dilute to 1000 mL with water): methanol = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA058\001-0101



The chromatogram of the test solution --- HPLC2\WA058\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clotrimazole	7.27	520.1	8599	/	1.13

# Clotrimazole Pellicles – 克霉唑药膜

Clotrimazole (100037-200306) – Method number WA059

## Assay

**Test solution:** Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 12.5 mg of clotrimazole, in a 25 mL volumetric flask, add a quantity of methanol, treat ultrasonically for 10 minutes until the clotrimazole dissolves, allow to cool to room temperature, dilute with methanol to volume, shake well, filter and use the filtrate as the test solution.

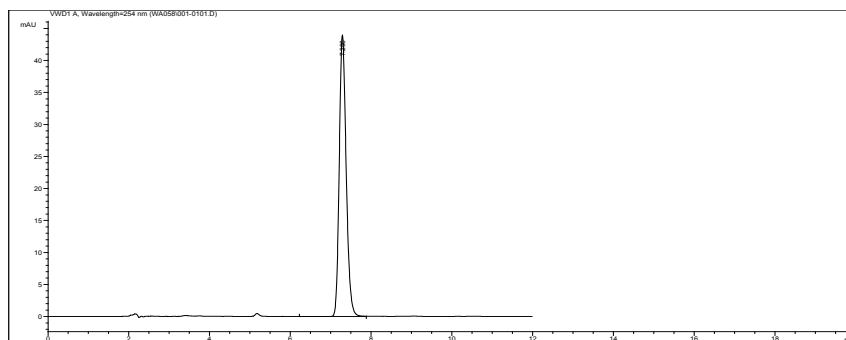
**Reference solution:** Repeat the procedure using clotrimazole CRS to produce the reference solution.

## Chromatographic conditions

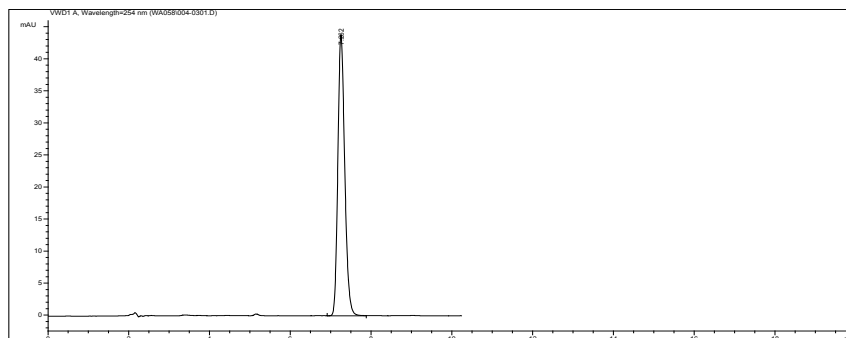
- Column : Agilent ZORBAX Extend-C18 4.6×250 mm, 5 µm (770450-902)
- Mobile phase: phosphate solution (dissolve 4.35 g dipotassium hydrogen phosphate and dilute to 1000 mL with water): methanol = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA058\001-0101



The chromatogram of the test solution --- HPLC2\ WA058\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clotrimazole	7.26	519.9	8590	/	1.16



# Ribavirin – 利巴韦林

Ribavirin (629-200202) – Method number WR034

## Assay

Test solution: Dissolve a quantity in mobile phase to produce a test solution of 0.4 mg/mL.

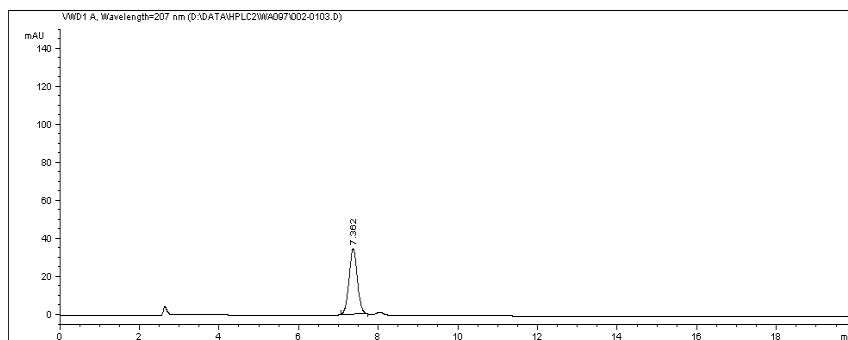
Reference solution: Dissolve a quantity in mobile phase to produce a reference solution of 4 µg/mL.

## Chromatographic conditions

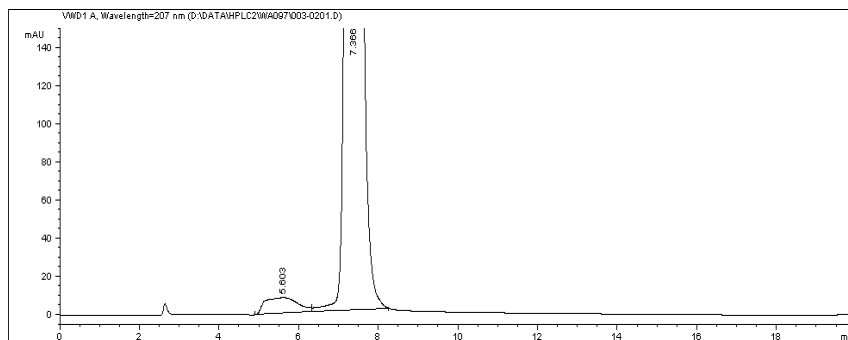
- Column: packed with hydrogen cation- exchange resin HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2WA097002-0103.D



The chromatogram of the test solution--- HPLC2WA097003-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.37	48867.6	5776	1.7	1.05
Impurity	5.60	482.0	/	/	1.09

# Ribavirin Nasal Drops – 利巴韦林滴鼻液

Ribavirin (629-200202) – Method number WR039

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase to produce a test solution of 50 µg/mL.

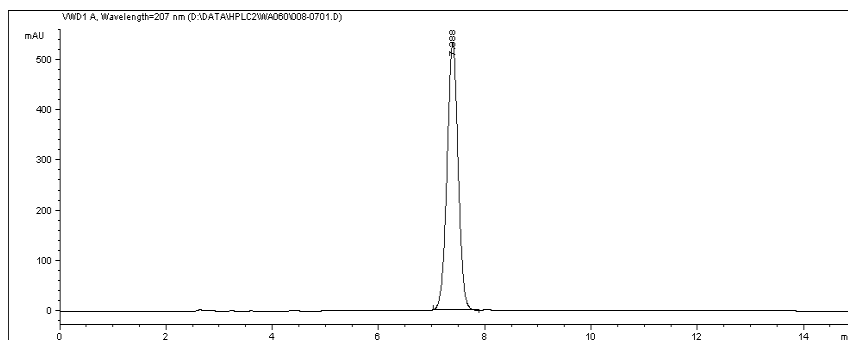
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

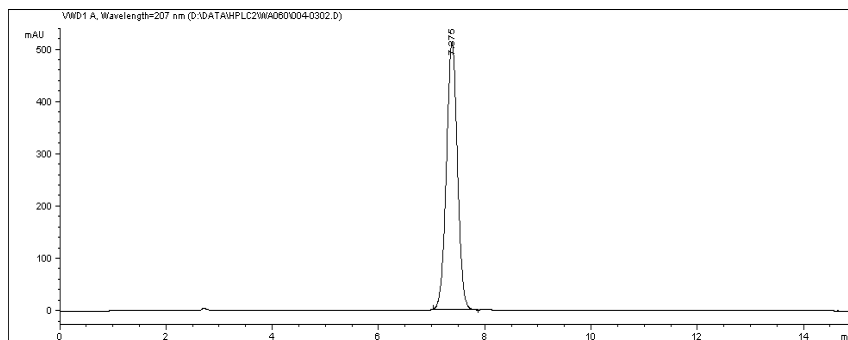
- Column: packed with hydrogen cation- exchange resin HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2WA060008-0701.D D



The chromatogram of the test solution--- HPLC2WA060004-0302.D D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.38	7460.4	6189		1.00

# Ribavirin Eye Drops – 利巴韦林滴眼液

Ribavirin (629-200202) – Method number WR038

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase to produce a test solution of 50 µg/mL.

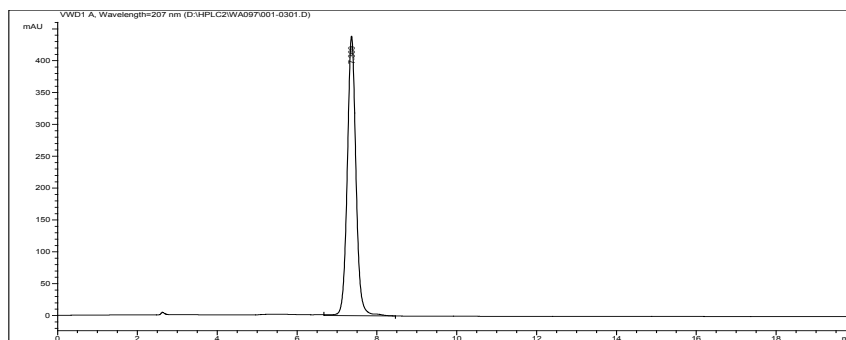
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

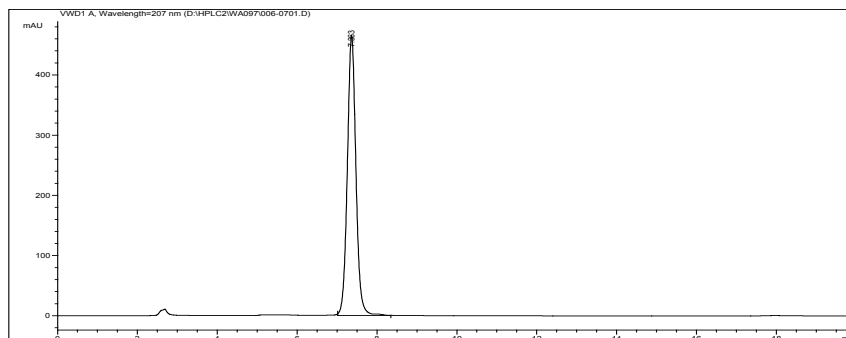
- Column: packed with hydrogen cation- exchange resin HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2WA097001-0301.D



The chromatogram of the test solution--- HPLC2WA097006-0702.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.36	6968.1	5772	/	1.05

# Ribavirin Buccal Tablets – 利巴韦林含片

Ribavirin (629-200202) – Method number WA266

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase to produce a solution of 50 µg of ribavirin per mL, shake thoroughly, filter and use as the test solution.

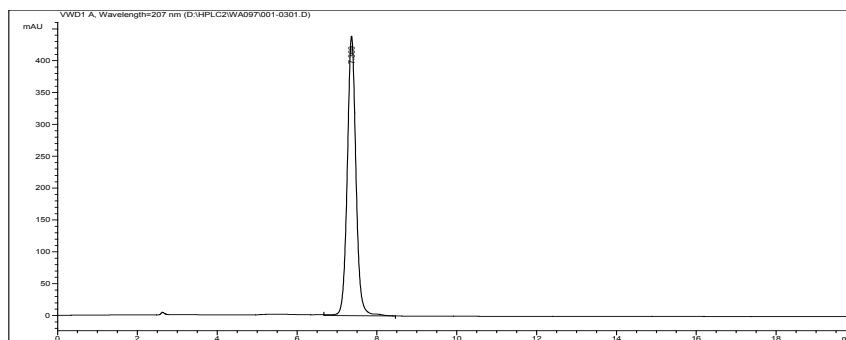
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

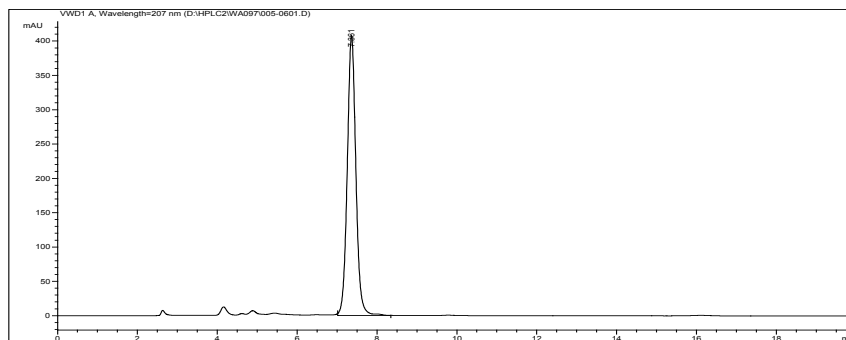
- Column: a column packed with hydrogen cation-exchange resin HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution -- HPLC2\WA097\001-0301.D



The chromatogram of the test solution --- HPLC2\WA097\005-0601.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.36	5984.7	6025	/	1.05

# Ribavirin Capsules – 利巴韦林胶囊

Ribavirin (629-200202) – Method number WA060

## Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, dissolve and dilute with the mobile phase to produce a solution of 50 µg of ribavirin per mL, mix well, filter and use the filtrate as the test solution.

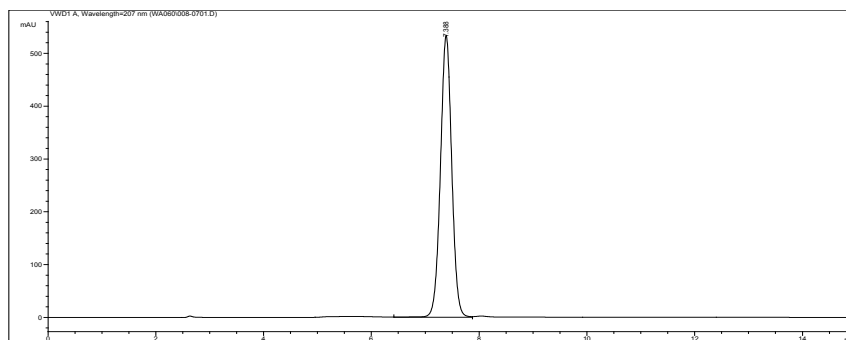
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

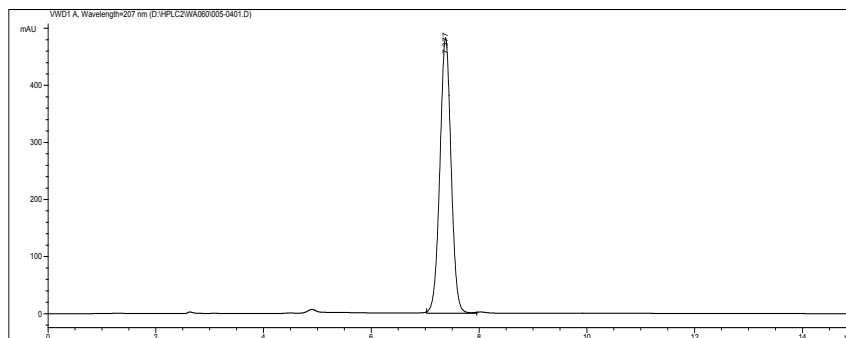
- Column: hydrogen cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA060\008-0701



The chromatogram of the test solution --- HPLC1\ WA060\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.38	6995.0	5794	/	1.01

# Ribavirin Granules – 利巴韦林颗粒

Ribavirin (629-200202) – Method number WA062

## Assay

Test solution: Grind to a fine powder. Dissolve and dilute an accurately measured quantity of the powder with mobile phase to produce a solution of 50 µg of ribavirin per mL, mix well, filter and use the filtrate as the test solution.

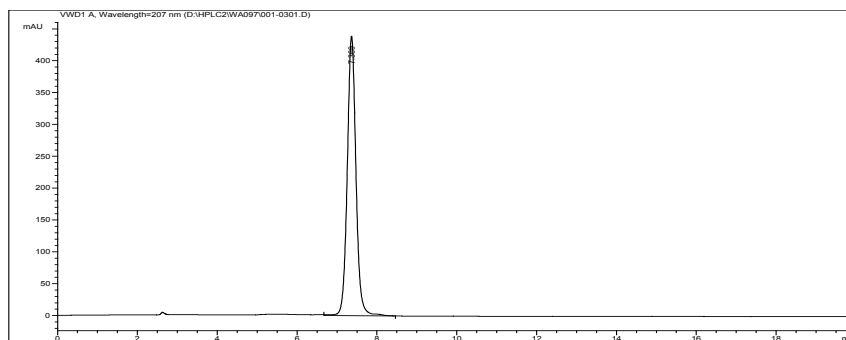
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

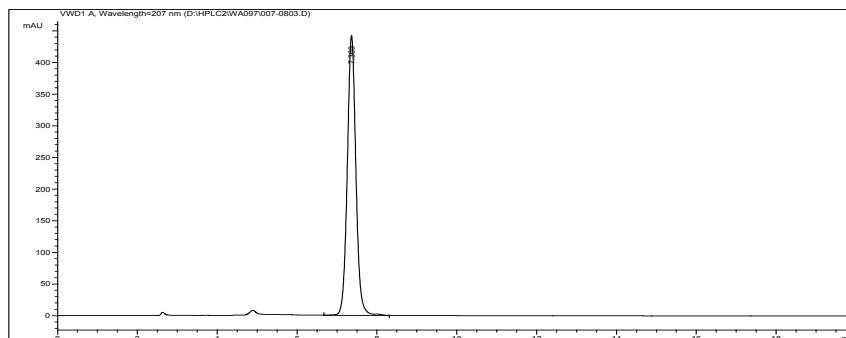
- Column: hydrogen cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate : 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA097\001-0301



The chromatogram of the test solution--- HPLC2\ WA097\007-0803

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.37	6606.5	6028	/	1.05

# Ribavirin and Sodium Chloride Injection – 利巴韦林氯化钠注射液

## Ribavirin (629-200202) – Method number WA063

### Assay

Test solution: Accurately measure a quantity of the injection, dilute with mobile phase to produce a test solution of 50 µg of ribavirin per mL.

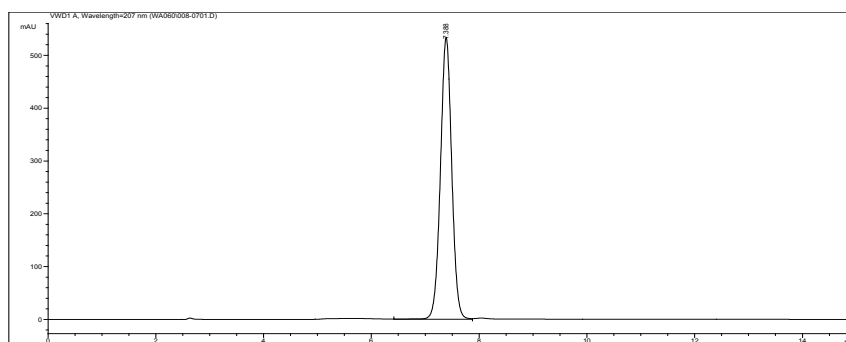
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

### Chromatographic conditions

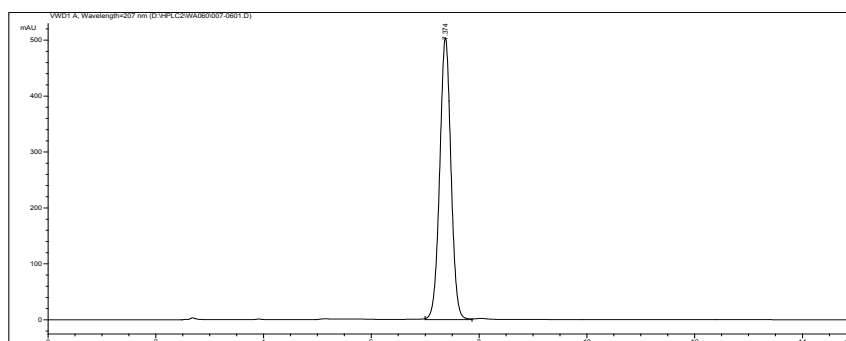
- Column: hydrogen cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA060\008-0701



The chromatogram of the test solution--- HPLC1\ WA060\007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ribavirin	7.37	7304.6	6315	/	1.01

# Ribavirin and Sodium Chloride Injection – 利巴韦林氯化钠注射液

## Ribavirin (629-200202) – Method number WA063

### Assay

Test solution: Dilute an accurately measured quantity of the injection fluid with mobile phase to produce a test solution containing 0.4 mg/mL.

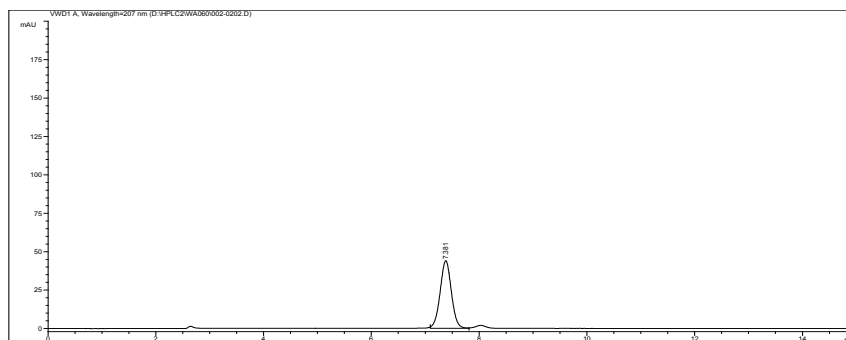
Reference solution: Dilute an accurately measured quantity of the injection fluid with mobile phase to produce a reference solution containing 4 µg/mL.

### Chromatographic conditions

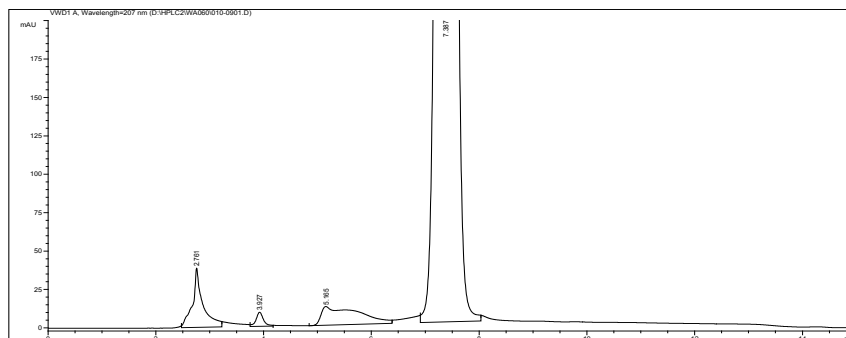
- Column: hydrogen cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA060\002-0202



The chromatogram of the test solution--- HPLC1\WA060\010-0901

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ribavirin	7.39	52078.1	5457	/	1.00
Impurity1	3.93	87.5	4875	5.4	/
Impurity2	5.17	586.5	/	/	/



# Ribavirin Tablets – 利巴韦林片

## Ribavirin (629-200202) – Method number WR035

### Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase to produce a solution of 50 µg/mL, mix well, filter and use the filtrate as the test solution.

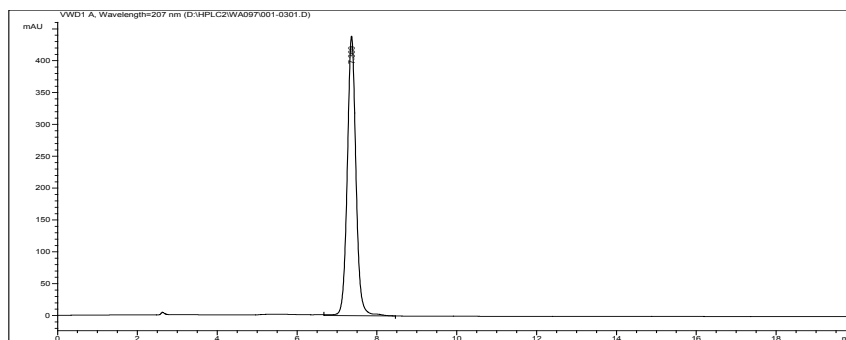
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

### Chromatographic conditions

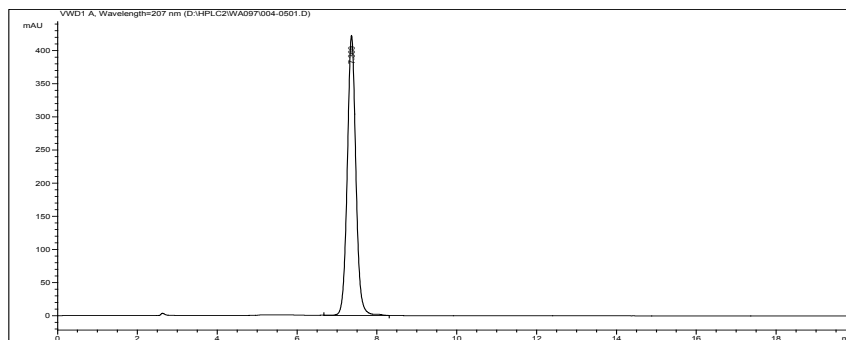
- Column: packed with hydrogen cation- exchange resin
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2WA097001-0301.D



The chromatogram of the test solution--- HPLC2WA097004-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.37	6337.7	5319	/	1.05

# Ribavirin and Glucose Injection – 利巴韦林葡萄糖注射液

Ribavirin (629-200202)– Method number WA061

## Assay

Test solution: Accurately measure a quantity of the injection fluid, add mobile phase to produce the test solution of 50 µg of ribavirin per mL.

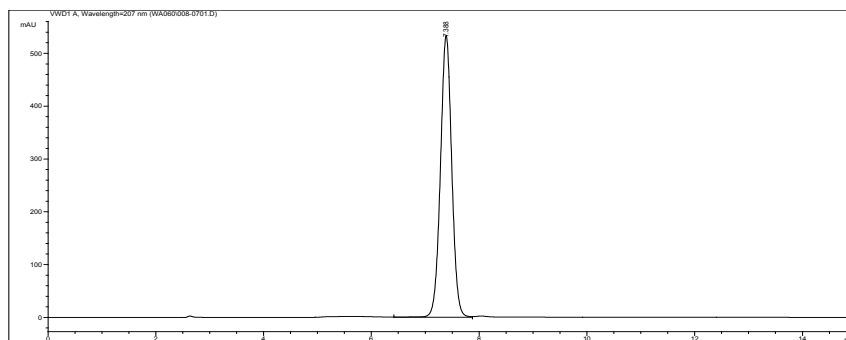
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

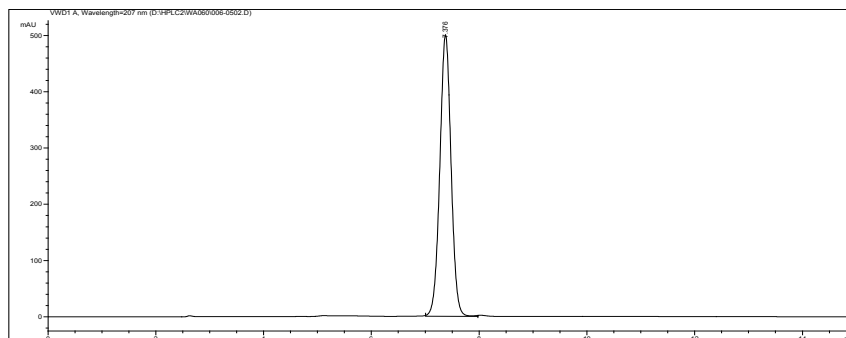
- Column : hydrogen cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer HC-75H+
- Mobile phase: water(adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate : 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA061\008-0701



The chromatogram of the test solution --- HPLC1\ WA061\006-0502

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ribavirin	7.38	7240.6	6181	/	1.01

# Ribavirin and Glucose Injection – 利巴韦林葡萄糖注射液

Ribavirin (629-200202) – Method number WA061

## Assay

Test solution: Dilute an accurately measured quantity of the injection fluid with mobile phase to produce the test solution containing 0.4 mg/mL.

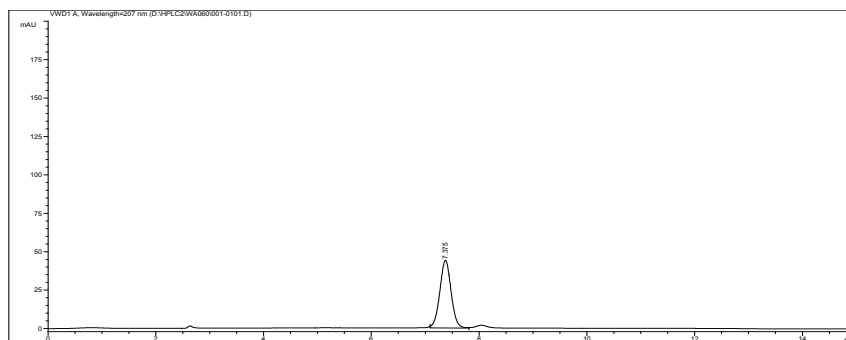
Reference solution: Dilute an accurately measured quantity of the injection fluid with mobile phase to produce the reference solution containing 4 µg/mL.

## Chromatographic conditions

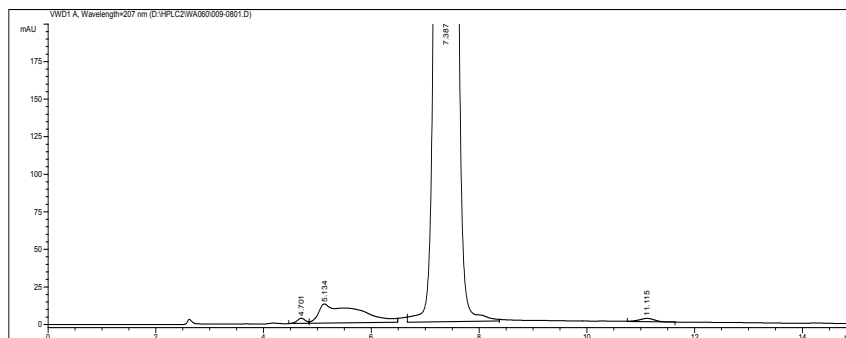
- Column :hydrogen cation-exchange resin consisting of sulfonated cross-linked styrene-divinglbenzene copolymer HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate : 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA061\001-0101



The chromatogram of the test solution--- HPLC1\ WA061\009-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.39	51985.0	5456	/	1.00
Impurity1	4.70	37.1	4304	/	0.92
Impurity2	5.13	670.9	/	/	/
Impurity3	11.12	42.9	7321	8.10	0.87

# Ribavirin Injection – 利巴韦林注射液

Ribavirin (629-200202) – Method number WR037

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase to produce the test solution containing 50 µg/mL.

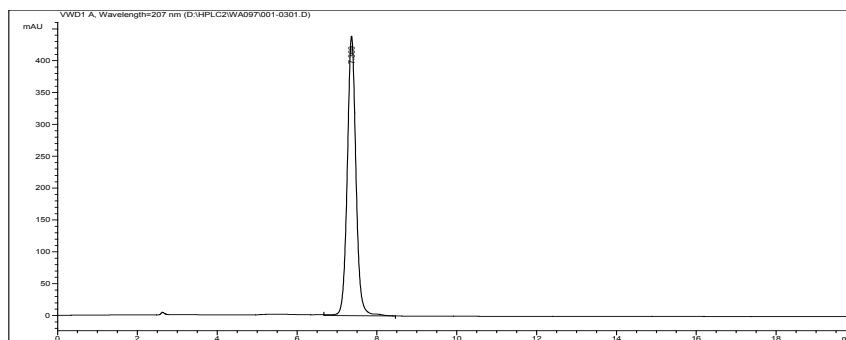
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

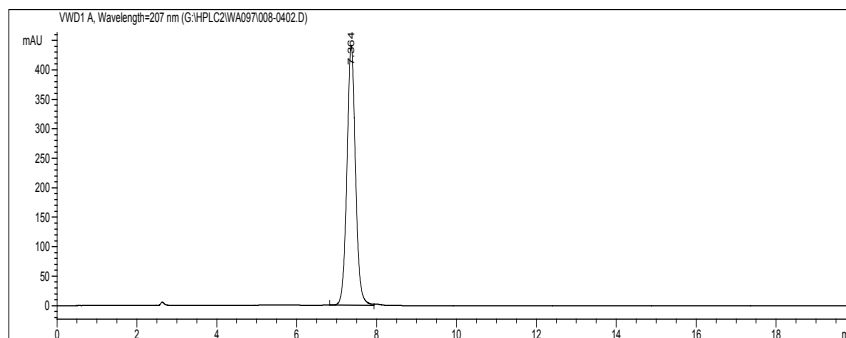
- Column: packed with hydrogen cation- exchange resin
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2WA097001-0301.D



The chromatogram of the test solution--- HPLC2WA097008-0402.D D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ribavirin	7.36	6493.7	6161	/	1.05

# Ribavirin Injection – 利巴韦林注射液

Ribavirin (629-200202) – Method number WR037

## Assay

Test solution: Dilute an accurately measured quantity of the injection fluid with mobile phase to produce the test solution containing 0.4 mg/mL.

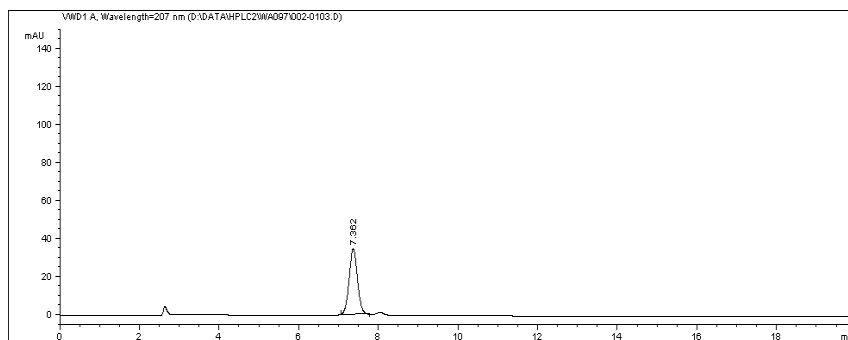
Reference solution: Dilute an accurately measured quantity of the injection fluid with mobile phase to produce the reference solution containing 4 µg/mL.

## Chromatographic conditions

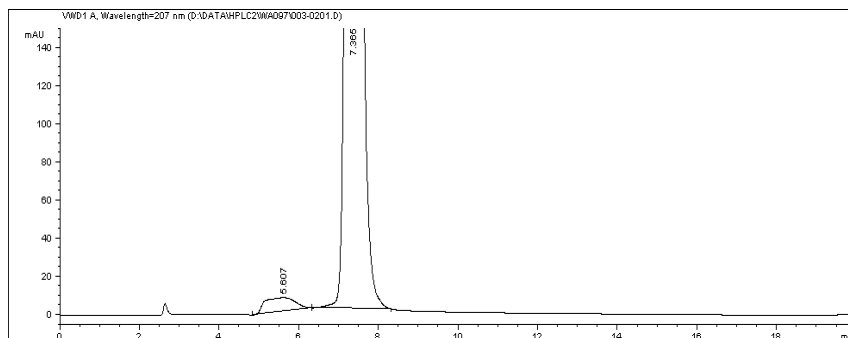
- Column: packed with hydrogen cation-exchange resin HC-75H+
- Mobile phase: water (adjust pH to  $2.5 \pm 0.1$  with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2WA097002-0103.D



The chromatogram of the test solution--- HPLC2WA097003-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ribavirin	7.37	48755.4	5776	1.8	1.05
Impurity	5.61	385.6	/	/	1.11

# Rifampicin – 利福平

Rifampicin (130496-2000010) – Method number WR162

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in acetonitrile to produce the test solution of 1 mg/mL.

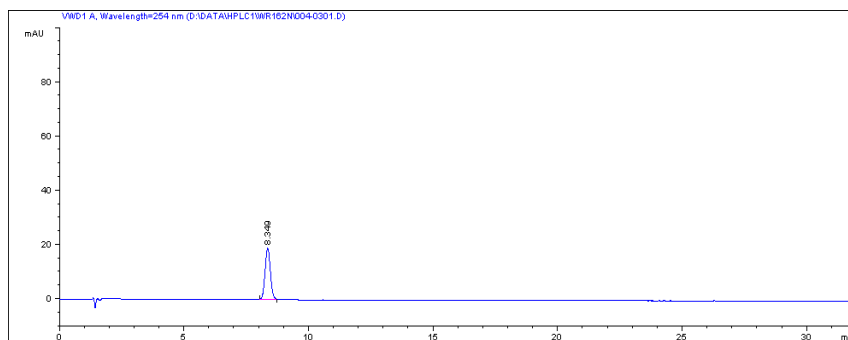
Reference solution: Dissolve an accurately weighed quantity of rifampicin CRS in acetonitrile to produce the reference solution of 0.01 mg/mL.

## Chromatographic conditions

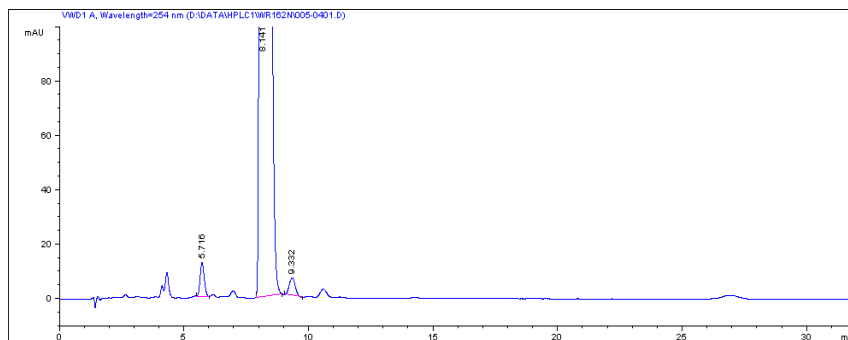
- Column: Agilent ZORBAX XDB-C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: 75 mM potassium dihydrogen phosphate: 1 M citric acid : methanol : acetonitrile = 40:4:28:28
- Flow rate: 1.0 mL/min Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR162N004-0301.D



The chromatogram of the test solution --- HPLC1\WR162N005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clotrimazole	7.31	586.4	7671	/	1/13

# Rifampicin Capsules – 利福平胶囊

Rifampicin (130496-2000010) – Method number WR041

## Assay

Test solution: Accurately weigh a quantity of well-mixed contents, equivalent to about 80 mg of rifampicin, add acetonitrile to produce a solution of 0.8 mg/mL. Filter through a millipore membrane (0.45 µm), accurately measure a quantity of the filtrate in a mixture of acetonitrile-water (1:1) to produce the test solution of 0.08 mg/mL.

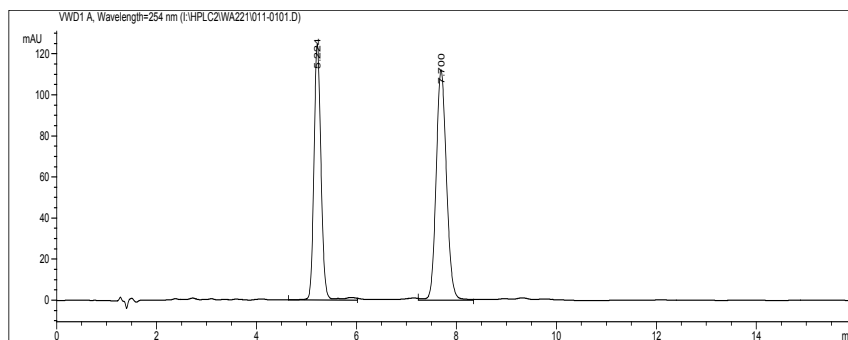
Reference solution: Produce the reference solution using a quantity of rifampicin CRS, in which concentration is equivalent to the test solution.

## Chromatographic conditions

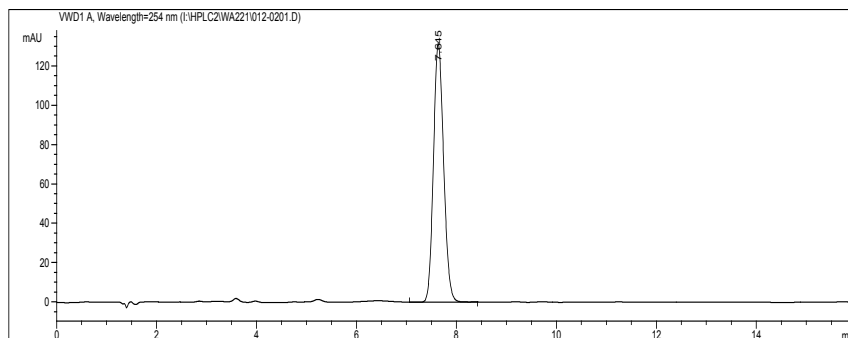
- Column: Agilent ZORBAX XDB-C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: 75 mM potassium dihydrogen phosphate: 1 M citric acid:methanol: acetonitrile = 40:4:28:28
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability-- HPLC2\WA221\011-0101.D



The chromatogram of the test solution--- HPLC2\WA221\012-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Rifampicin Quinone	5.22	1185.0	6815	/	1.08
Rifampicin	7.70	1594.5	6309	7.5	1.08

# Rifampicin Capsules – 利福平胶囊

## Rifampicin (130496-2000010) – Method number WR041

### Assay

Test solution: Accurately weigh a quantity of well-mixed contents, equivalent to about 125mg of rifampicin, add acetonitrile to produce a solution of 5 mg/mL. Filter through a millipore membrane (0.45 µm), accurately measure a quantity of the filtrate in acetonitrile to produce the test solution of 1 mg/mL.

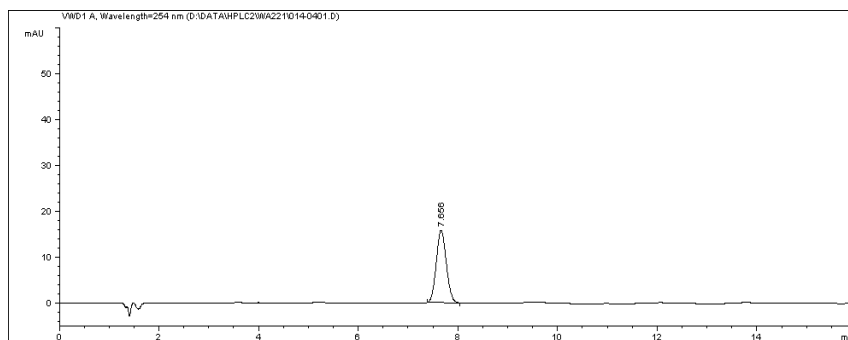
Reference solution: Dissolve an accurately weighed quantity of rifampicin CRS in acetonitrile to produce a solution of 0.05 mg/mL. Dilute an accurately measured quantity of this solution with a mixture of acetonitrile-water (1:1) to produce the reference solution of 10 µg/mL.

### Chromatographic conditions

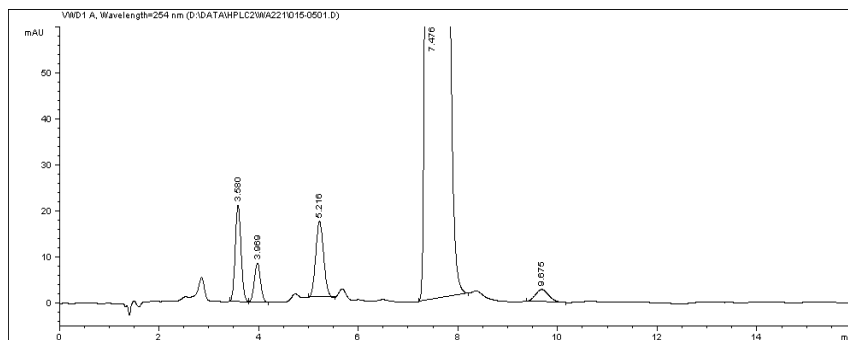
- Column: Agilent ZORBAX XDB-C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: 75 mM potassium dihydrogen phosphate: 1 M citric acid:methanol: acetonitrile = 40:4:28:28
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution-- HPLC2WA221\014-0401.D



The chromatogram of the test solution--- HPLC2WA221\015-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Rifampicin Quinone	5.22	182.1	5126	4.8	1.08
Rifampicin	7.48	21980.9	5365	6.5	1.68
Impurity1	3.58	171.7	4460	/	1.06
Impurity2	3.97	74.1	4726	1.7	1.02



# Benproperine Phosphate Granules – 磷酸苯丙哌林颗粒

## Benproperine Phosphate (0237-9701) – Method number WA228

### Assay

Test solution: Grind the contents to a fine powder and mix well. Accurately weigh a quantity of the powder, equivalent to about 20 mg of benproperine phosphate, in a 50 mL volumetric flask, dissolve the benproperine phosphate in 20 mL of water, add 2.5 mL of 2 % sodium hydroxide solution, shake for 1 minute until a white precipitate is produced, add 10 ml of 4 % phosphoric acid solution to make the precipitate disappear, dilute with water to volume, mix well, filter and use the filtrate as the test solution.

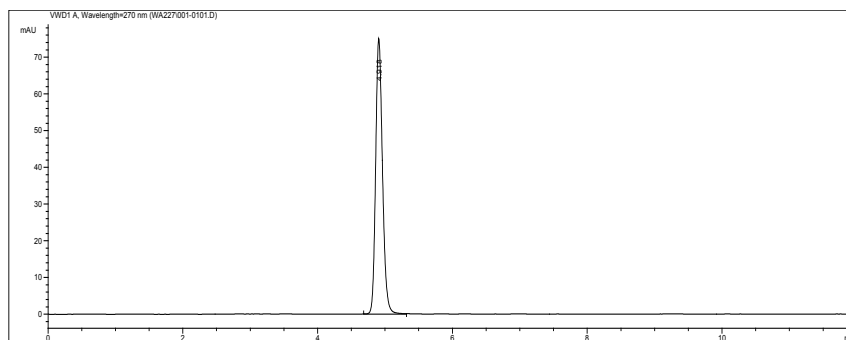
Reference solution: Repeat the procedure using benproperine phosphate CRS to produce the reference solution.

### Chromatographic conditions

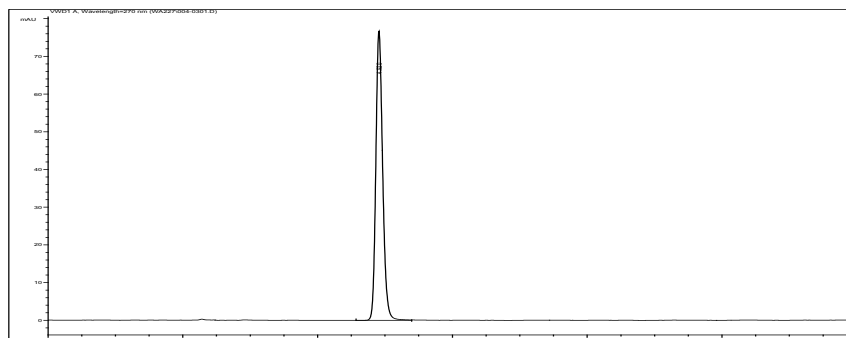
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol: 0.1 M ammonium acetate BS (dissolve 7.7 g of ammonium acetate in 800 mL of water, adjust pH to 3.3 with glacial acetic acid, add water to 1000 mL) = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature: 30 °C
- Detector wavelength: 270 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA227\001-0101



The chromatogram of the test solution --- HPLC1\WA227\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Benproperine Phosphate	4.92	540.1	9615	/	1.09

# Benproperine Phosphate Oral Solution – 磷酸苯丙哌林口服液

## Benproperine Phosphate (0237-9701) – Method number WA227

### Assay

**Test solution:** Accurately measure 2 mL of the solution in a 100 mL volumetric flask, dilute with a mixture of methanol-water (70:30) to volume and mix well. Accurately measure 5 mL in a 50 mL volumetric flask, dilute with a mixture of methanol-water (70:30) to volume, mix well and use as the test solution.

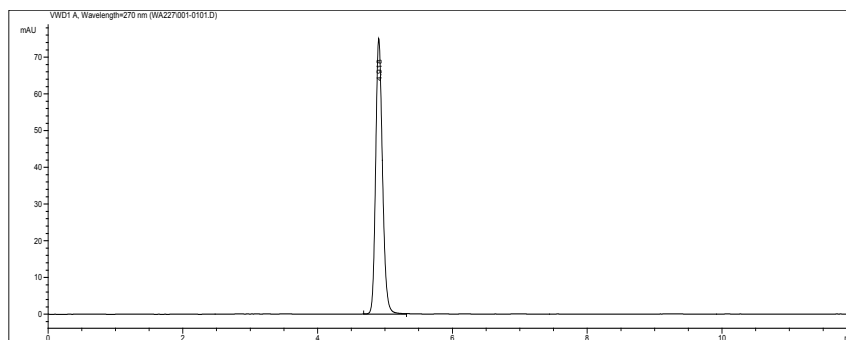
**Reference solution:** Dilute a quantity of benproperine phosphate CRS with a mixture of methanol-water (70:30) to produce the reference solution containing 0.4 mg/mL.

### Chromatographic conditions

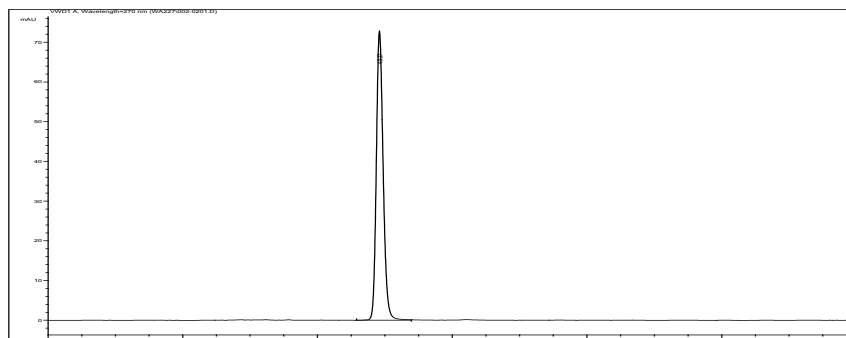
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 μm (880975-914)
- Mobile phase: methanol: 0.1 M ammonium acetate BS (dissolve 7.7 g of ammonium acetate in 800 mL of water, adjust pH to 3.3 with glacial acetic acid, add water to 1000 mL) = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 5 μL
- Column temperature: 30 °C
- Detector wavelength: 270 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA227\001-0101



The chromatogram of the test solution --- HPLC1\WA227\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Benproperine Phosphate	4.93	514.4	10194	/	1.10

# Ligustrazine Phosphate – 磷酸川芎嗪

## Ligustrazine phosphate – Method number WA226

### Assay

Test solution: Dissolve an accurately weighed quantity of the substance in water to produce the test solution of 500 µg/mL.

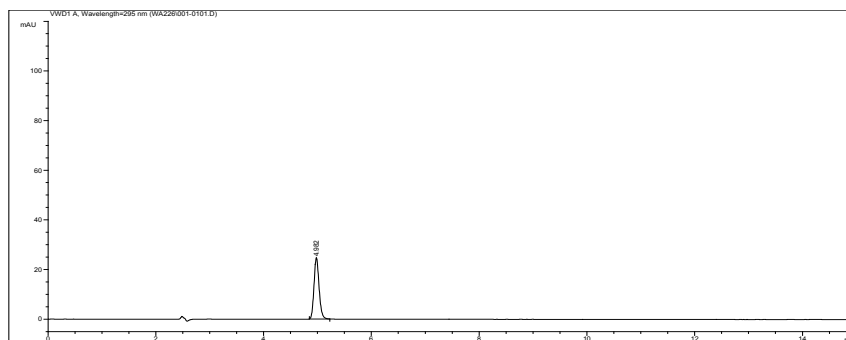
Reference solution: Dilute an accurately measured quantity of the test solution with water to produce the reference solution of 5 µg/mL.

### Chromatographic conditions

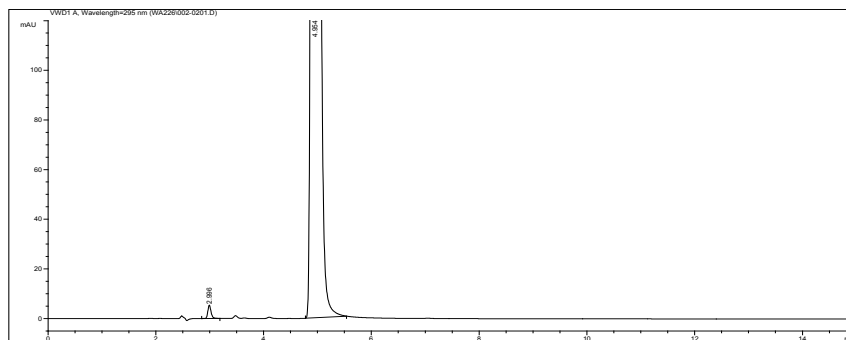
- Column: Agilent ZORBAX Bonus-RP 4.6x250 mm, 5 mm (880668-901)
- Mobile phase: methanol:water = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 295 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA226\001-0101.D



The chromatogram of the test solution--- HPLC1\WA226\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ligustrazine Phosphate	4.95	15117.7	13089	13.9	1.16
Impurity	3.0	22.2	12492	/	1.19

# Vindesine Sulfate – 硫酸长春地辛

Vindesine sulfate – Method number WA215

## Assay

Test solution: Dilute a quantity of the substance with water to produce the test solution containing 1 mg/mL.

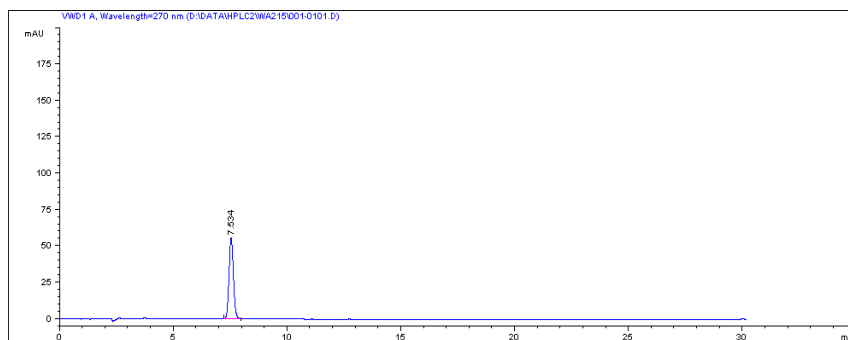
Reference solution: Dilute a quantity of the substance with water to produce the reference solution containing 0.04 mg/mL.

## Chromatographic conditions

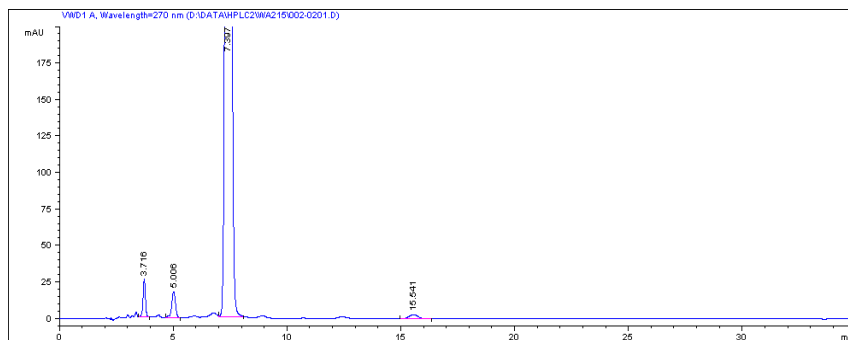
- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.02 mol/L dipotassium hydrogen phosphate solution (adjust pH to 6.62 with phosphoric acid):methanol = 25:75
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 270 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA215\001-0101



The chromatogram of the test solution---HPLC2\WA215\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vindesine Sulfate	7.40	19828.7	7296	7.4	1.08
Impurity1	3.72	188.2	6710	/	0.91
Impurity2	5.01	193.5	4632	5.4	0.90
Impurity3	15.5	78.3	7864	15.5	1.00

# Gentamycin Sulfate – 硫酸庆大霉素

## Gentamycin (30326-200314) – Method number WA213

### Assay

Test solution: Dissolve an accurately weighed quantity of the substance to produce the test solution.

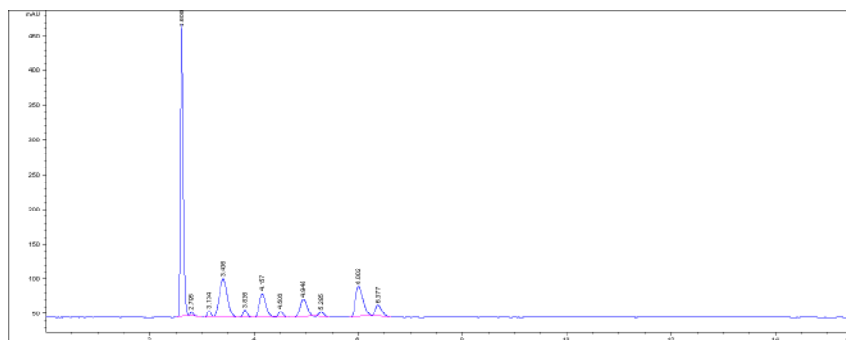
Reference solution: Dissolve an accurately weighed quantity of gentamycin CRS to produce a reference solution of 1.0 mg/mL.

### Chromatographic conditions

- Column: ZORBAX SB-Aq C18, 4.6×250 mm, 5 µm (880975-914)
- Column temperature: 35 °C
- Mobile phase: 1 % trifluoroacetate solution
- Evaporator tube temperature: 115 °C
- Injection volume: 20 µL
- Air flow rate: 3.5 mL/min
- Flow rate : 1.0 mL/min

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution

Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	R <sub>s</sub>
Gentamycin	0.043	2.608	418.87	1690.3	9734	1.07

# Salbutamol Sulfate Sustained-release Capsules

Salbutamol sulfate (10328-0002) – Method number WA322

硫酸沙丁胺醇缓释胶囊

## Assay

Test solution: Grind the contents to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 8 mg of salbutamol, in a 100 mL volumetric flask, add a quantity of 0.1 mol/L dilute hydrochloric acid, treat ultrasonically for 15 minutes to dissolve the salbutamol sulfate, allow to cool, dilute with 0.1 mol/L dilute hydrochloric acid to volume, mix well, filter and use the filtrate as the test solution.

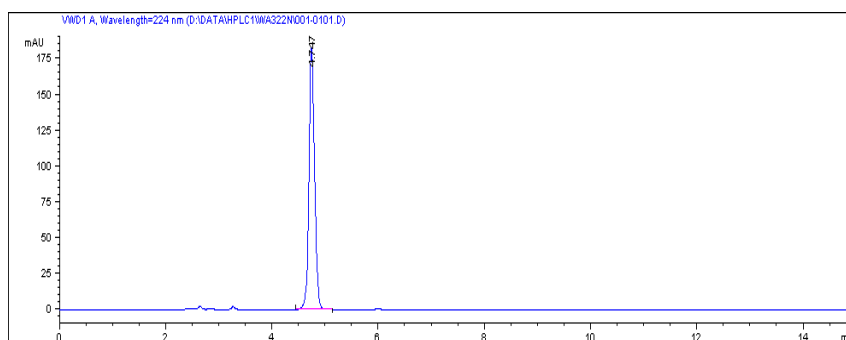
Reference solution: Repeat the procedure using salbutamol sulfate CRS to produce the reference solution of 80 µg/mL.

## Chromatographic conditions

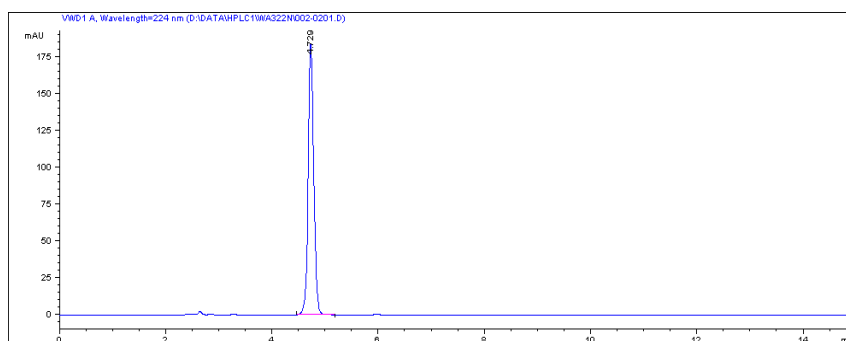
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol:0.005 mol/L ammonium biphosphate solution (pH=3.0) = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 224 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA322N001-0101



The chromatogram of the test solution --- HPLC1\WA322N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Salbutamol Sulfate	4.73	1347.1	10545	/	1.04

# Micronomicin Sulfate Injection – 硫酸小诺霉素注射液

Micronomicin (3429404) – Method number WA320

## Assay

Test solution: Dilute an accurately measured volume of the injection fluid with water to produce the test solution of 1.0 mg of micronomicin per mL.

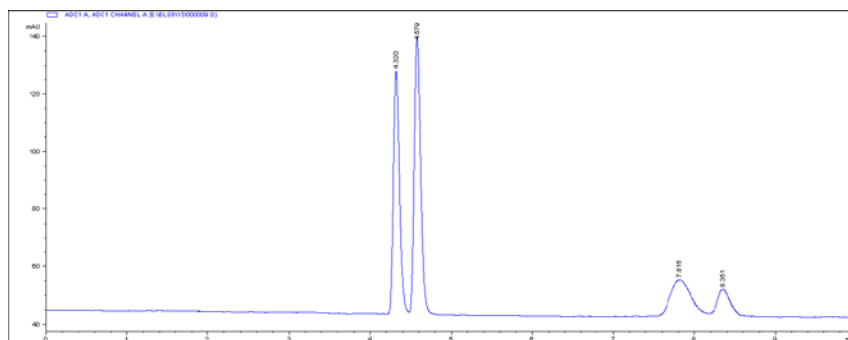
Reference solution: Repeat the procedure to produce the reference solution.

## Chromatographic conditions

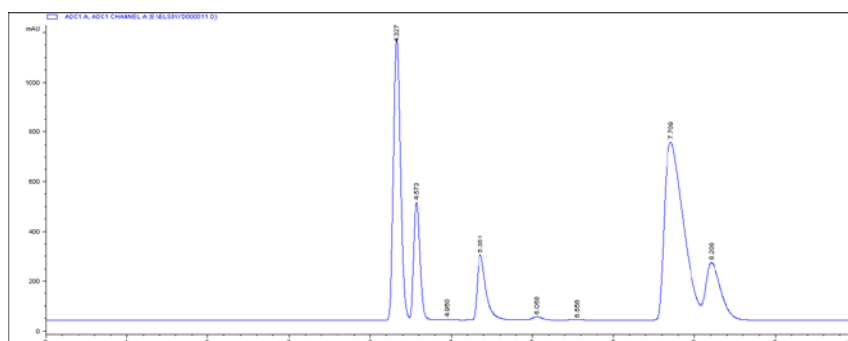
- Column: ZORBAX SB-Aq 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 1 % trifluoroacetic acid solution
- Flow rate: 0.6 mL/min Injection volume: 20 µL
- Column temperature: 20 °C
- Evaporator tube temperature: 115 °C
- Air flow rate: 3.5 mL/min

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution



The chromatogram of the test solution

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Component 1	4.321	432.5	17594		1.2
Component 2	4.585	519.0	18201	1.99	1.1
Component 3	7.793	247.8	4449	10.62	1.3
Component 4	8.349	117.6	13902	1.50	1.1

# Etimicin Sulfate – 硫酸依替米星

Etimicin (130365-200301) Netilmicin (0355-200001) – Method number WA216

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in water to produce the test solution of 1.0 mg/mL.

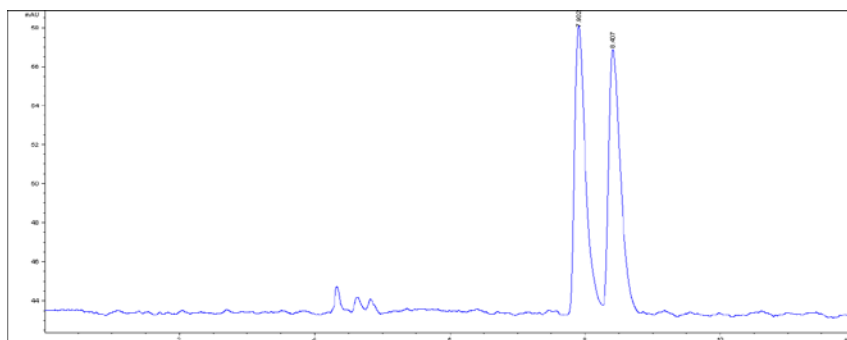
Reference solution: Dissolve accurately weighed quantities in water to produce the reference solution of 0.3 mg each of etimicin and netilmicin per mL.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 1 % trifluoroacetate solution
- Evaporator tube temperature: 115 °C
- Air flow rate: 3.5 mL/min
- Flow rate: 0.6 mL/min
- Injection volume: 20 µL
- Column temperature: 20 °C

## Chromatographic system

- Binary Pump (G1312A)
- Manual Injector (G1328B)
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD Alltech 2000
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution

Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	R <sub>s</sub>
Etimicin	7.902	14.78	166.4	12208		
Netilmicin	8.407	13.47	163.5	11440	1.678	



# Etimicin Sulfate Injection – 硫酸依替米星注射液

Etimicin, Netilmicin – Method number WA323

## Assay

Test solution: Dilute an accurately measured volume of the injection fluid with water to produce the test solution of 0.5 mg of etimicin per mL.

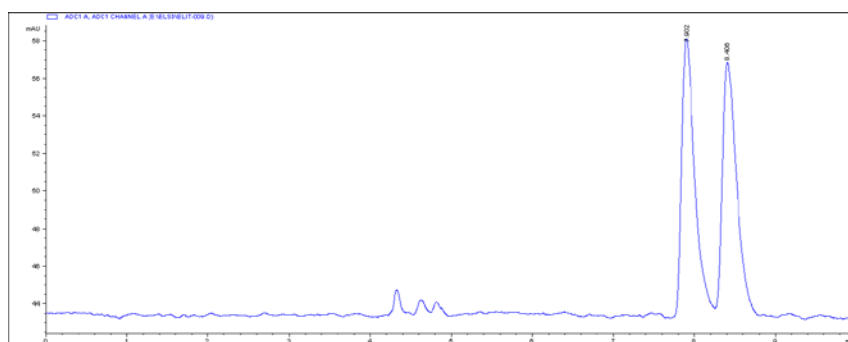
Reference solution: repeat the procedure to produce the reference solution.

## Chromatographic conditions

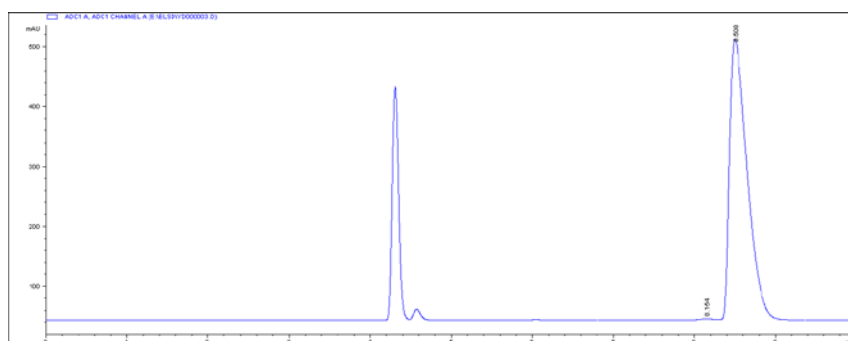
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 1 % trifluoroacetate solution
- Evaporator tube temperature: 115 °C
- Air flow rate: 2.0 mL/min
- Flow rate: 0.6 mL/min
- Injection volume: 20 µL
- Column temperature: 20 °C

## Chromatographic system

- Binary Pump (G1312A)
- Manual Injector (G1328B)
- Agilent 1200 Series thermostated column compartment
- Agilent 35900 A/D converter
- ELSD Alltech 2000
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability



The chromatogram of the test solution

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Netilmicin	8.102	926.4	14818		1.2
Etimicin	8.642	2096.6	11874	1.85	1.3

# Azathioprine – 硫唑嘌呤

## Azathioprine 6-mercaptopurine (ACROS) – Method number WA213

### Assay

Test solution: Dissolve about 25 mg of the substance in 3 mL of dimethylsulfoxide, dilute with mobile phase to produce the test solution of about 250 µg/mL.

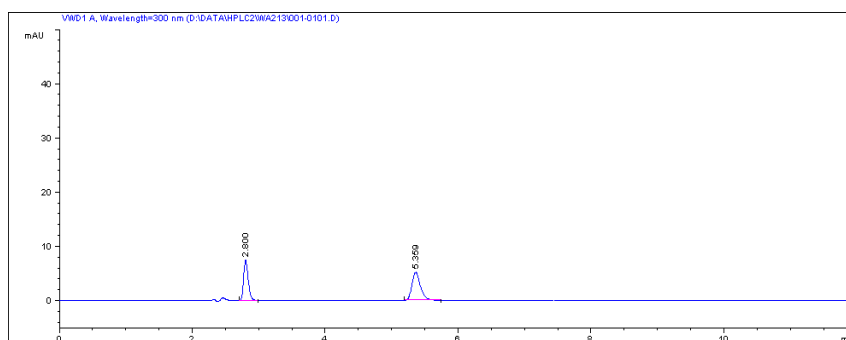
Reference solution: Accurately measure 1 mL of the test solution, dilute with mobile phase to 100 mL, mix well and use as the reference solution. Dilute a quantity of 6-mercaptopurine CRS with mobile phase to produce the reference solution of 2.5 µg of azathioprine and 1.25 µg of 6-mercaptopurine per mL.

### Chromatographic conditions

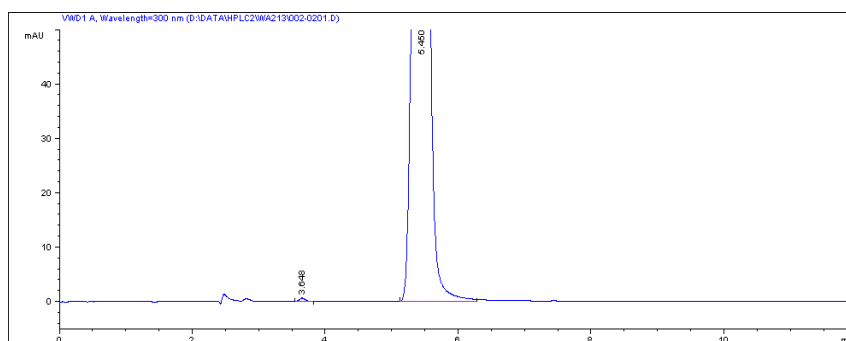
- Column: Agilent ZORBAX Extend-C18 4.6×250 mm, 5 µm (770450-902)
- Mobile phase: methanol: 0.05: sodium acetate = 25:75
- Flow rate: 1.0 mL/min Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 300 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA213\001-0101



The chromatogram of the test solution --- HPLC2\WA213\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
6-Mercaptopurine	2.81	3.7	3678	/	/
Azathioprine	5.45	4320.4	7510	8.7	0.93

# Chloramphenicol – 氯霉素

Chloramphenicol (0303-9613) – Method number WR113

## Assay

Test solution: Dissolve an accurately weighed quantity in methanol, adding 1 mL of methanol per 10 mg of chloramphenicol, dilute with mobile phase and mix well to produce the test solution of 100 µg/mL.

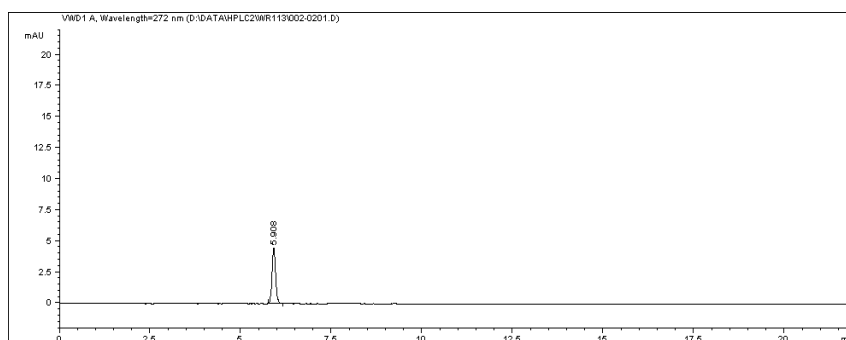
Reference solution: Dissolve an accurately weighed quantity of chloramphenicol-diol in methanol, adding 1 mL of methanol per 10 mg of chloramphenicol-diol, dilute with mobile phase to produce the reference solution of 1 µg/mL.

## Chromatographic conditions

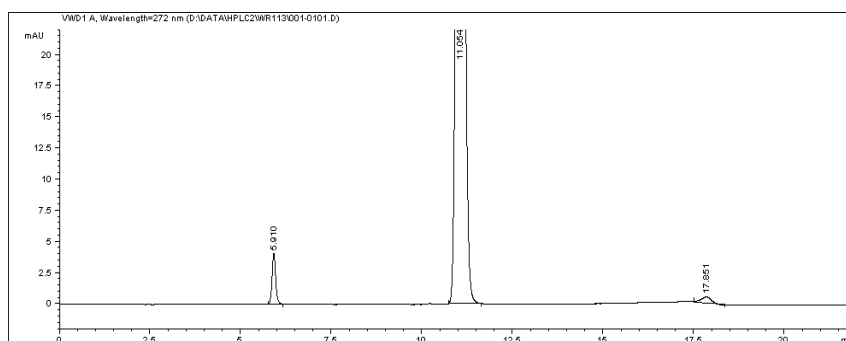
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium heptanesulfonate dimethyl- formamide solution(mix 500 mL of 0.1 % sodium heptanesulfonate, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid) : acetonitrile (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR113002-0201.D



The chromatogram of the test solution--- HPLC2WR113001-0101.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Chloramphenicol	11.05	1697.9	19903	20.7	1.07
Chloramphenicol-diol	5.91	28.8	16973	/	1.14
4-nitro benzaldehyde	17.85	10.6	15517	15.3	0.85

# Chloramphenicol Ear Drops – 氯霉素滴耳液

Chloramphenicol (0303-9613) – Method number WR116

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase and mix well to produce the test solution of 100 µg/mL.

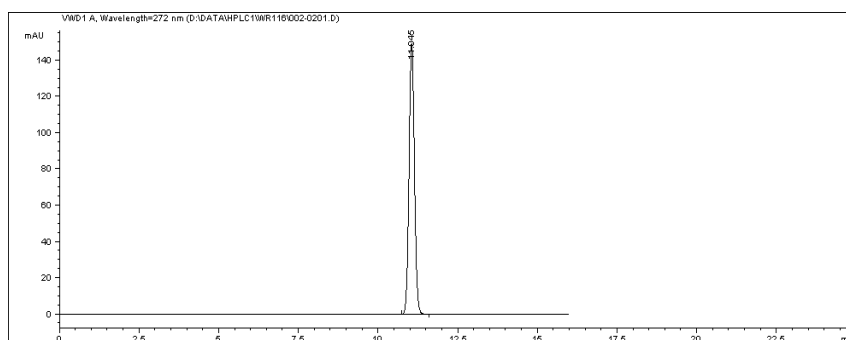
Reference solution: Produce the reference solution using chloramphenicol CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

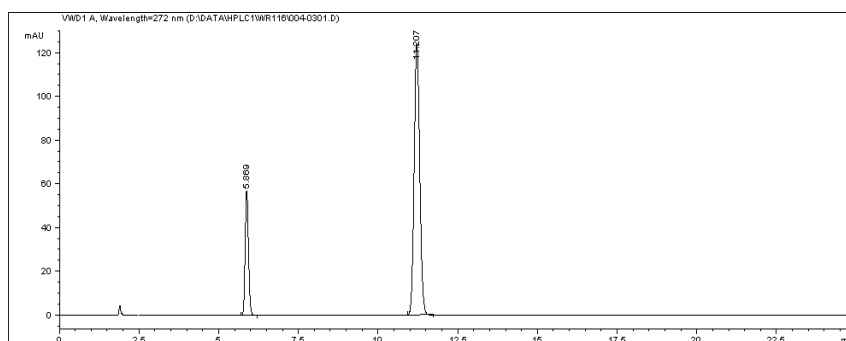
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium heptanesulfonate dimethyl- formamide solution (mix 500 mL of 0.1 % sodium heptanesulfonate, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid) : acetonitrile (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR116\002-0201.D



The chromatogram of the test solution-- HPLC1\WR116\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Chloramphenicol	11.21	1530.2	19426	20.6	1.06

# Chloramphenicol Ear Drops – 氯霉素滴耳液

Chloramphenicol (0303-9613) – Method number WR116

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase and mix well to produce the test solution of 200 µg/mL.

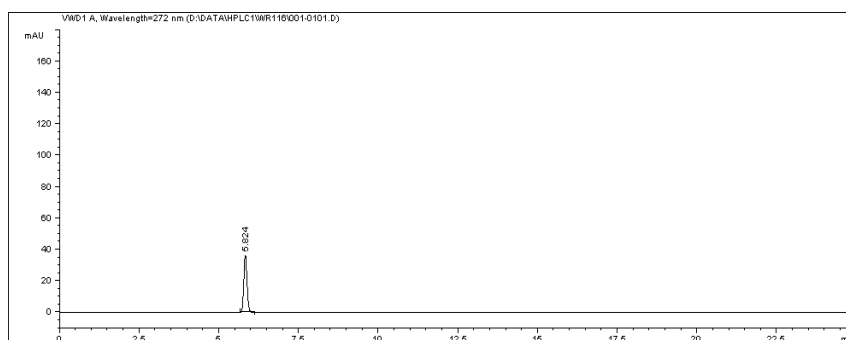
Reference solution: Dissolve an accurately weighed quantity of chloramphenicol-diol CRS in methanol, adding 1 mL of methanol per 10 mg of chloramphenicol-diol, dilute with mobile phase to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

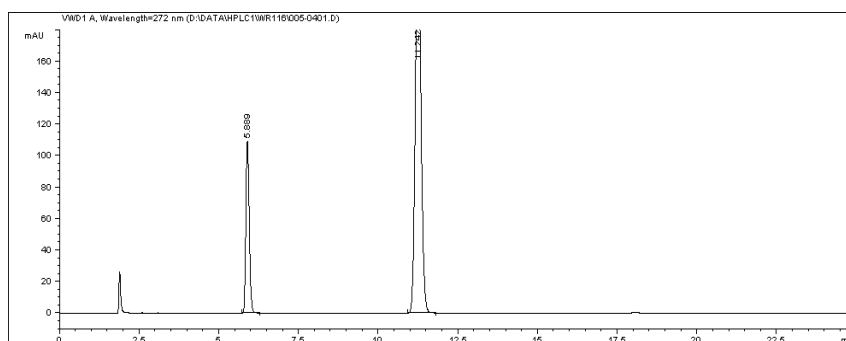
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium heptanesulfonate dimethyl- formamide solution (mix 500 mL of 0.1 % sodium heptanesulfonate, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid) : acetonitrile (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR116\001-0101.D



The chromatogram of the test solution--- HPLC1\WR116\005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Chloramphenicol	11.24	3018.5	19541	20.1	1.09
Chloramphenicol-diol	5.89	811.2	14979	/	1.20

# Chloramphenicol Eye Drops – 氯霉素滴眼液

Chloramphenicol (0303-9613) – Method number WR117

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase and mix well to produce the test solution of 100 µg/mL.

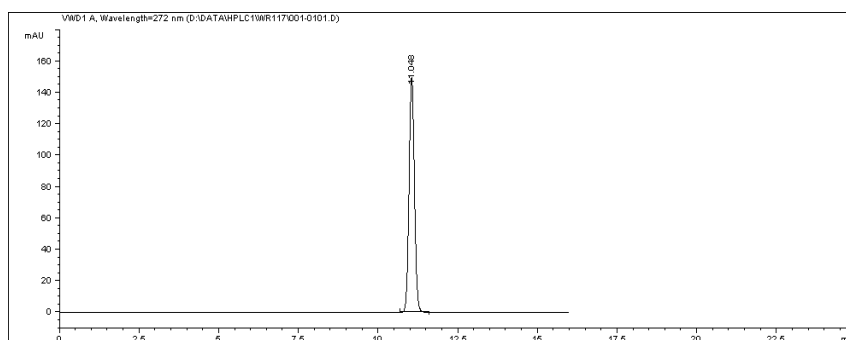
Reference solution: Produce the reference solution using Chloramphenicol CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

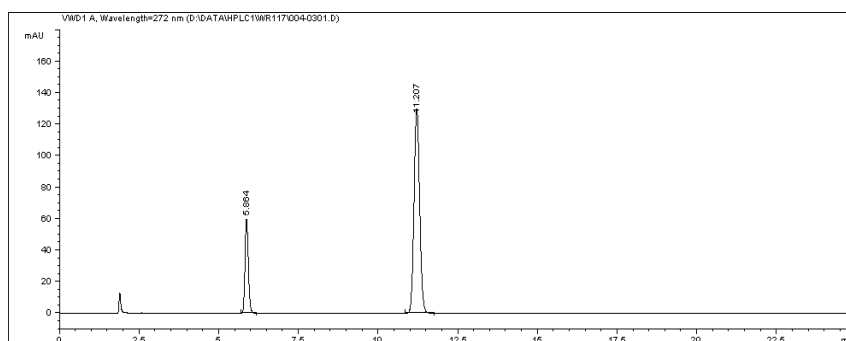
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium heptanesulfonate dimethyl- formamide solution (mix 500 mL of 0.1 % sodium heptanesulfonate, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid) : acetonitrile (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR117\001-0101.D



The chromatogram of the test solution--- HPLC2\WR117\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Chloramphenicol	11.21	1601.7	18463	/	1.06

# Chloramphenicol Eye Drops – 氯霉素滴眼液

Chloramphenicol (0303-9613) – Method number WR117

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase to produce the test solution of 250 µg/mL.

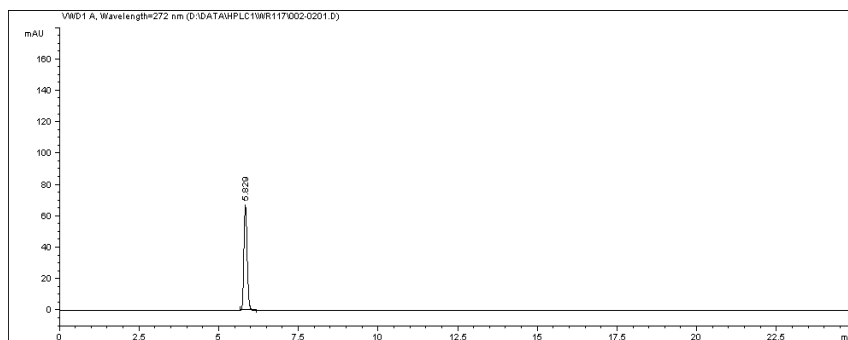
Reference solution: Dissolve an accurately weighed quantity of chloramphenicol-diol CRS in methanol, adding 1 mL of methanol per 10 mg of chloramphenicol-diol, dilute with mobile phase to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

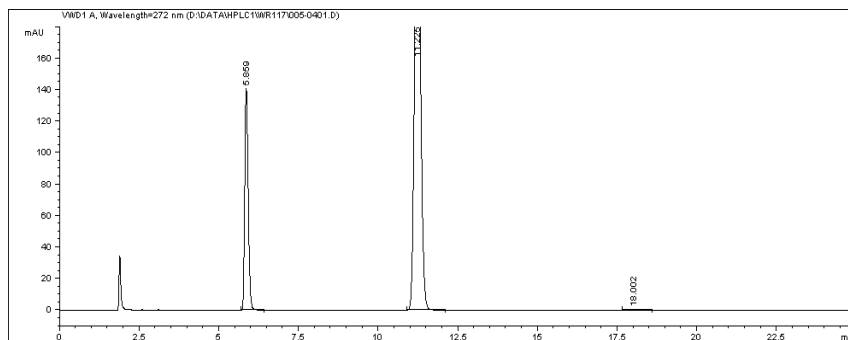
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium heptanesulfonate dimethyl-formamide solution (mix 500 mL of 0.1 % sodium heptanesulfonate, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid) acetonitrile(75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR117\002-0201.D



The chromatogram of the test solution--- HPLC2\WR117\005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Chloramphenicol	11.23	3931.7	18520	20.4	1.11
Chloramphenicol diol	5.86	1056.8	14414	/	1.20
4-nitro-benzaldehyde	18.00	3.8	16980	15.3	1.14

# Chloramphenicol Capsules – 氯霉素胶囊

## Chloramphenicol (0303-9613) – Method number WR114

### Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of chloramphenicol, dissolve in methanol, adding 1 mL of methanol per 10 mg of chloramphenicol, dilute with mobile phase to produce a solution of 100 µg/mL, shake well, filter and use the filtrate as the test solution.

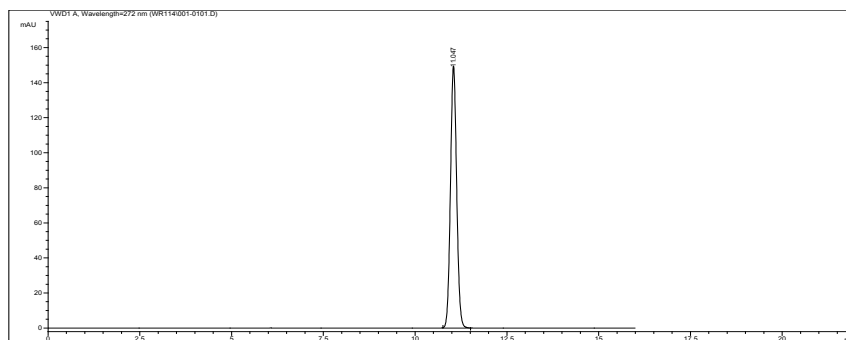
Reference solution: Produce the reference solution using chloramphenicol CRS, in which the concentration is equivalent to the test solution.

### Chromatographic conditions

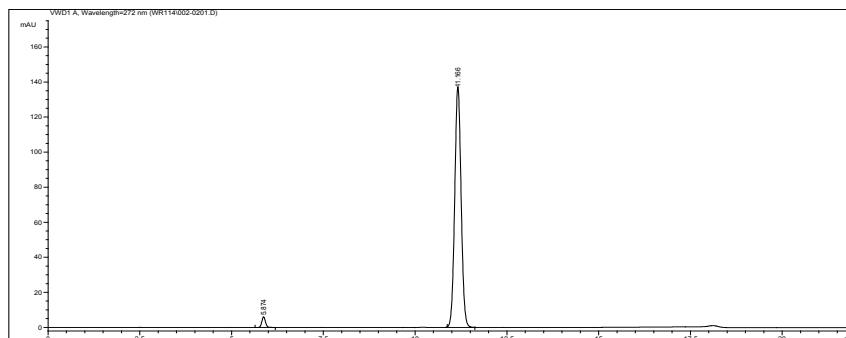
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium heptanesulfonate dimethyl- formamide solution (mix 500 mL of 0.1 % sodium heptanesulfonate, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid) : acetonitrile (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR114\001-0101.D



The chromatogram of the test solution--- HPLC1\WR114\002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Chloramphenicol	11.17	1665.3	19872	/	1.04



# Chloramphenicol Tablets – 氯霉素片

Chloramphenicol (0303-9613) – Method number WR198

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to about 50 mg of chloramphenicol, in methanol, adding 1 mL of methanol per 10 mg of chloramphenicol, dilute with mobile phase to produce the test solution of 0.1 mg/mL.

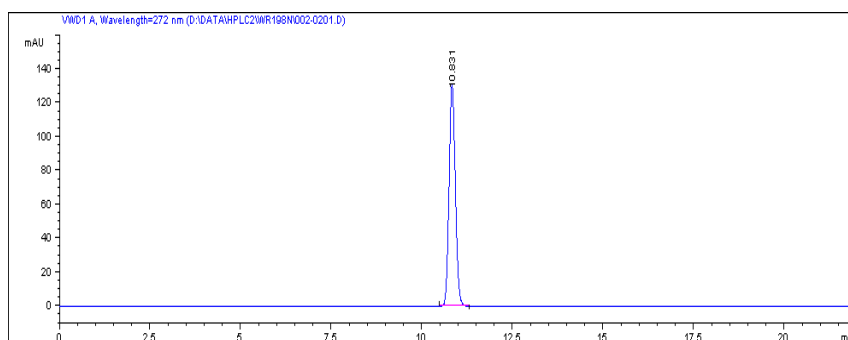
Reference solution: Dissolve a quantity of chloramphenicol CRS in mobile phase to produce the reference solution of 0.1 mg/mL.

## Chromatographic conditions

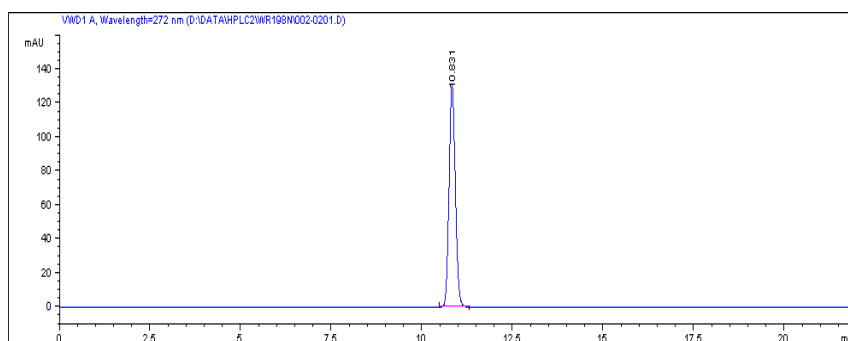
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.1 % sodium heptanesulfonate solution (mix 500 mL of 0.1 % sodium heptanesulfonate solution, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid): acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR198N\001-0101



The chromatogram of the test solution --- HPLC2\WR198N\002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Chloramphenicol	10.83	1580.8	18615	/	1.09

# Chloramphenicol Eye Ointment – 氯霉素眼膏

Chloramphenicol (0303-9613) – Method number WR115

## Assay

Test solution: Accurately weigh about 2 g in a separating funnel, add 30 mL of petroleum ether, shake to dissolve matrix, extract using three 20 ml quantities of phosphate BS (pH 6.0). Dilute the combined extracts to 100 ml with phosphate BS (pH 6.0), mix well and use as the test solution.

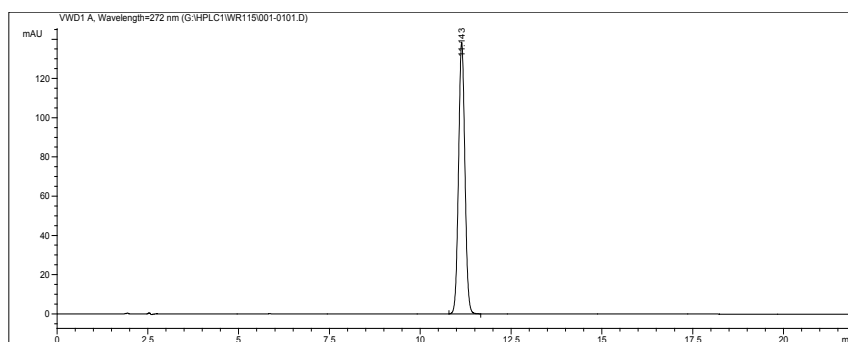
Reference solution: Accurately weigh about 50 mg of chloramphenicol CRS, dissolve in methanol, adding 1 mL of methanol per 10 mg of chloramphenicol, dilute with mobile phase and mix well to produce the reference solution of 100 µg per ml.

## Chromatographic conditions

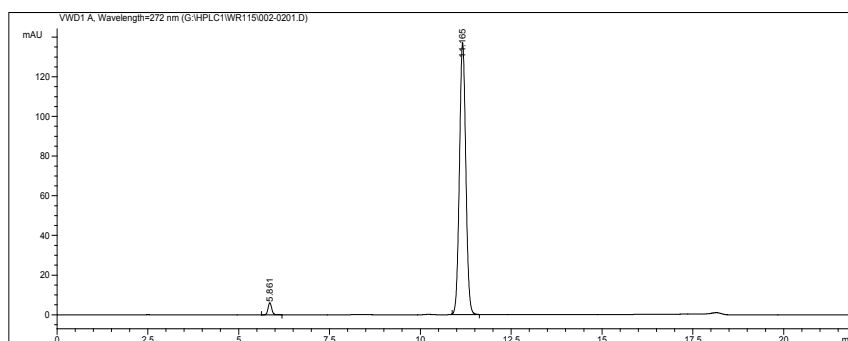
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: sodium heptanesulfonate dimethyl- formamide solution (mix 500 mL of 0.1 % sodium heptanesulfonate, 5 mL of dimethylformamide and 0.5 mL of glacial acetic acid) : acetonitrile (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 272 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WR115\001-0101



The chromatogram of the test solution---HPLC1\WR115\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Chloramphenicol	11.17	1664	20304	/	1.04

# Cloxacillin Sodium – 氯唑西林钠

Cloxacillin Sodium (0423-9902) – Method number WR112

## Assay

Test solution: Dissolve a quantity in mobile phase to produce the test solution containing 1 mg/mL.

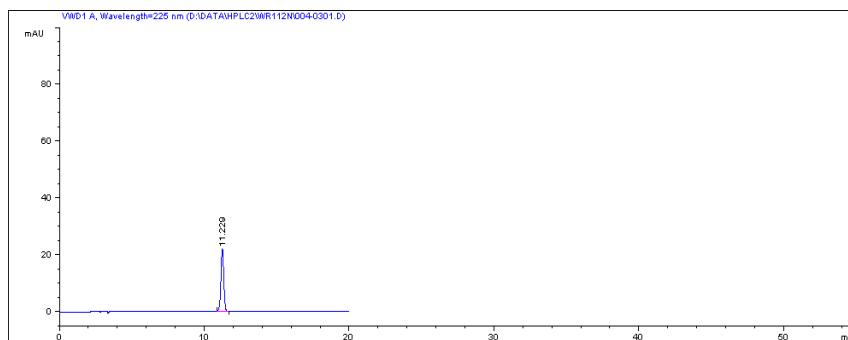
Reference solution: Dissolve a quantity in mobile phase to produce the reference solution containing 10 µg/mL.

## Chromatographic conditions

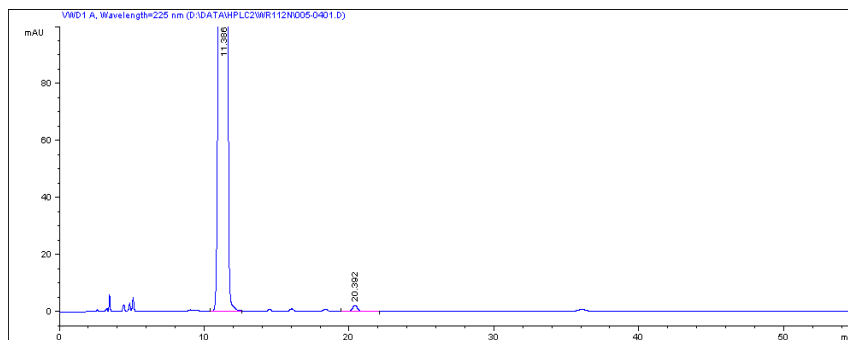
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.02 mol/L potassium dihydrogen phosphate solution (pH 5.0):acetonitrile = 75:25
- Flow rate: 1 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR112\N004-0301.D



The chromatogram of the test solution --- HPLC2\WR112\N005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cloxacillin Sodium	11.39	30518.1	3111	/	0.77
Impurity	20.39	57.6	15671	12.3	0.95

# Roxithromycin – 罗红霉素

Roxithromycin (130351-200303) – Method number WR067

## Assay

Test solution: Dissolve a quantity in mobile phase to produce the test solution of 2 mg/mL.

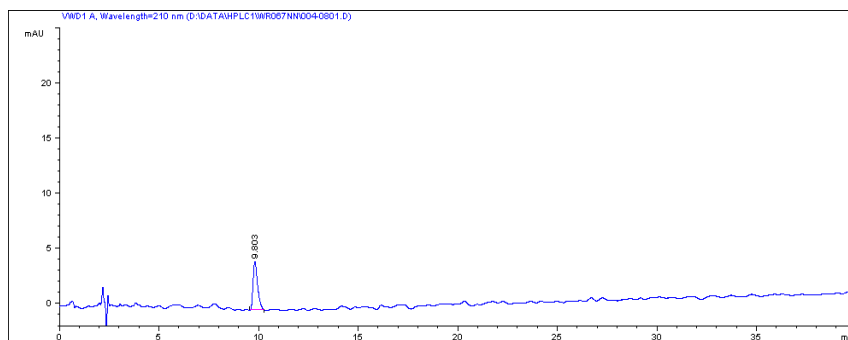
Reference solution: Dissolve a quantity in mobile phase to produce the reference of solution 20 µg/mL.

## Chromatographic conditions

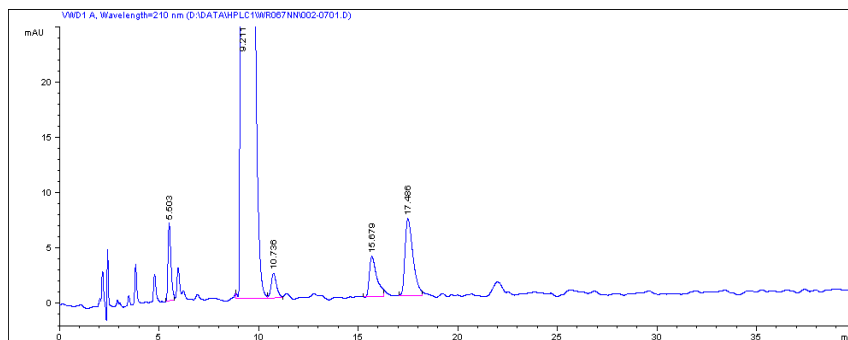
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.067 mol/L ammonium dihydrogen phosphate (adjust pH to 7.0 with triethylamine):acetonitrile=60: 40
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\ WR067NN004-0801.D



The chromatogram of the test solution--- HPLC2\WR067NN002-0701.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Roxithromycin	9.21	9565.0	3197	8.0	2.45
Impurity1	5.50	74.9	6814	/	1.52
Impurity2	10.74	44.4	7658	2.7	1.28
Impurity3	15.68	95.7	9572	8.8	1.70
Impurity4	17.49	196.7	9724	2.7	1.66

# Roxithromycin Dispersible Tablets – 罗红霉素分散片

Roxithromycin (130351-200303) – Method number WA274

## Assay

Test solution: Accurately weigh 10 tablets and grind to a powder. Dissolve an accurately weighed quantity of powder in mobile phase to produce a solution of 1 mg/mL, mix well, filter and use the filtrate as the test solution.

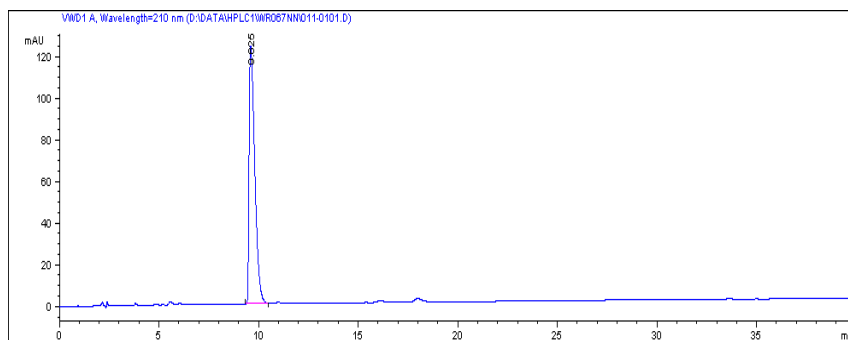
Reference solution: Produce the reference solution using roxithromycin CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

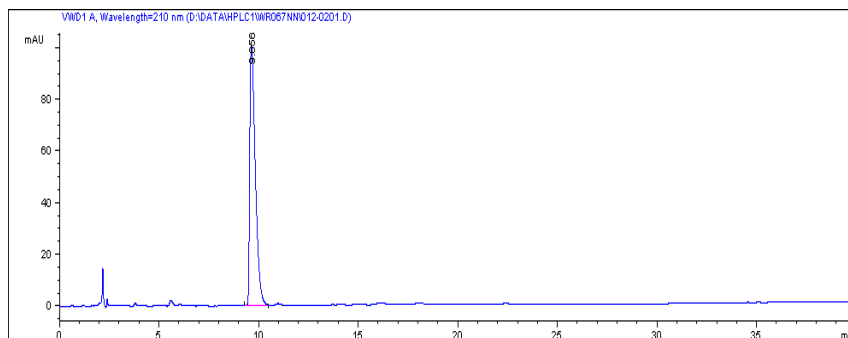
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.067 mol/L ammonium dihydrogen phosphate (adjust pH to 7.0 with triethylamine): acetonitrile= 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR067NN011-0101.D



The chromatogram of the test solution --- HPLC2\WR067NN012-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Roxithromycin	9.66	1961.5	5798	8.4	1.77

# Roxithromycin Dispersible Tablets – 罗红霉素分散片

Roxithromycin (130351-200303) – Method number WA274

## Assay

Test solution: Dissolve a quantity of powder in mobile phase to produce the test solution containing 2 mg/mL.

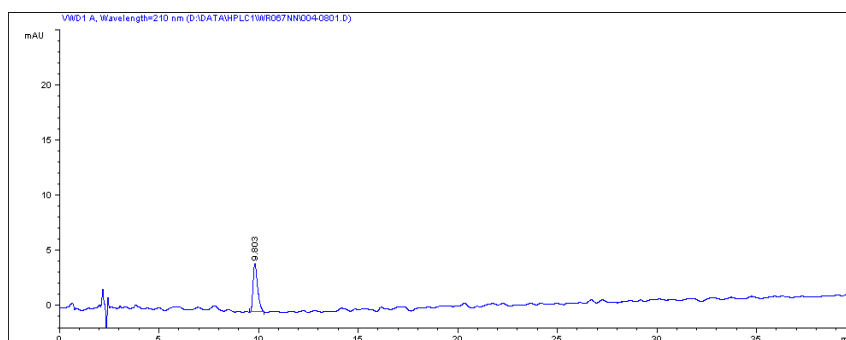
Reference solution: Dissolve a quantity of powder in mobile phase to produce the reference solution containing 20 µg/mL.

## Chromatographic conditions

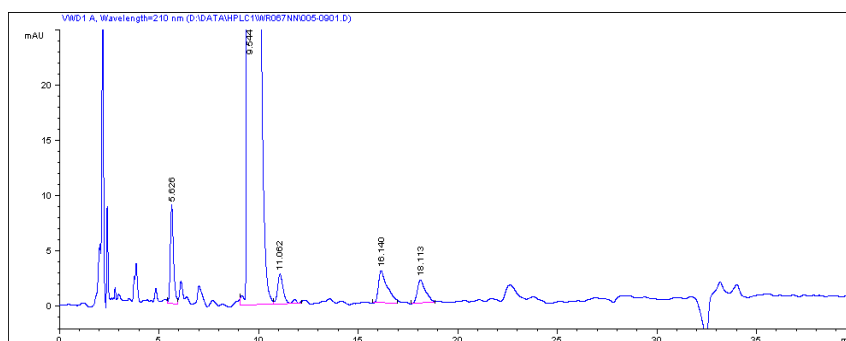
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.067 mol/L ammonium dihydrogen phosphate (adjust pH to 7.0 with triethylamine): acetonitrile = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR067NN004-0801.D



The chromatogram of the test solution --- HPLC2\WR067NN005-0901.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Roxithromycin	9.54	7846.0	3433	8.4	2.37
Impurity1	5.63	100.9	6567	/	1.39
Impurity2	11.06	58.5	8268	2.7	/
Impurity3	16.14	92.8	6934	8.0	1.94
Impurity4	18.11	61.8	9526	2.6	1.64

# Roxithromycin for Suspension – 罗红霉素干混悬剂

Roxithromycin (30495-200202) – Method number WA109

## Assay

Test solution: Dissolve an accurately weighed quantity of powdered, well-mixed contents in mobile phase, treat ultrasonically for 20 minutes, dilute with mobile phase to produce a solution of about 0.5 mg of roxithromycin per mL. Filter and use the filtrate as the test solution.

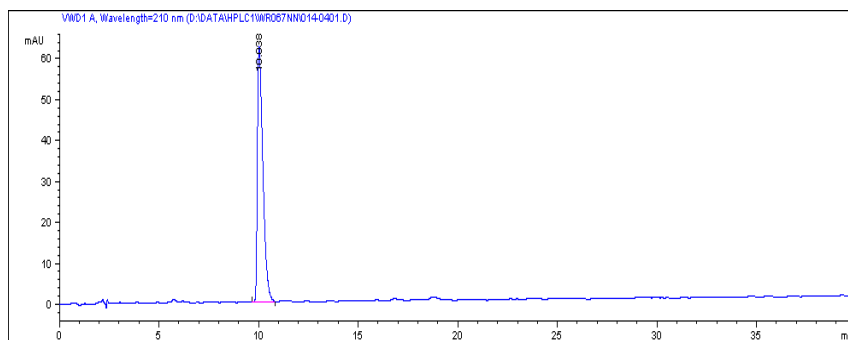
Reference solution: Repeat the procedure using roxithromycin CRS to produce the reference solution.

## Chromatographic conditions

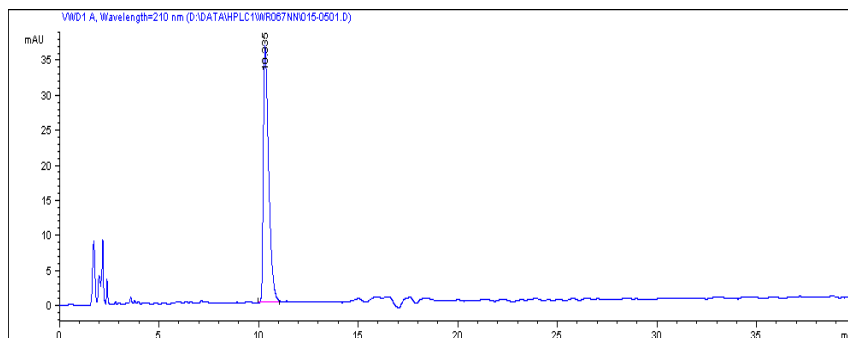
- Column : Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm
- (990967-902)
- Mobile phase: 0.067 mol/L ammonium dihydrogen phosphate (adjust to pH 7.0 with triethylamine): acetonitrile = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA109\001-0101



The chromatogram of the test solution --- HPLC1\ WA109\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Roxithromycin	10.33	689.2	7096	/	1.66

# Roxithromycin Capsules – 罗红霉素胶囊

## Roxithromycin (130351-200303) – Method number WR069

### Assay

**Test solution:** Add a quantity of mobile phase to an accurately weighed quantity of the well-mixed contents, treat ultrasonically for 20 minutes, dilute with mobile phase to produce a solution of 1 mg of roxithromycin per mL, filter and use the filtrate as the test solution.

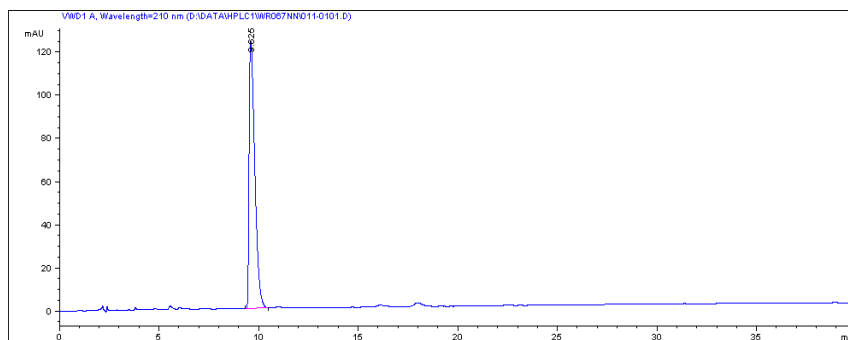
**Reference solution:** Produce the reference solution using roxithromycin CRS, in which the concentration is equivalent to the test solution.

### Chromatographic conditions

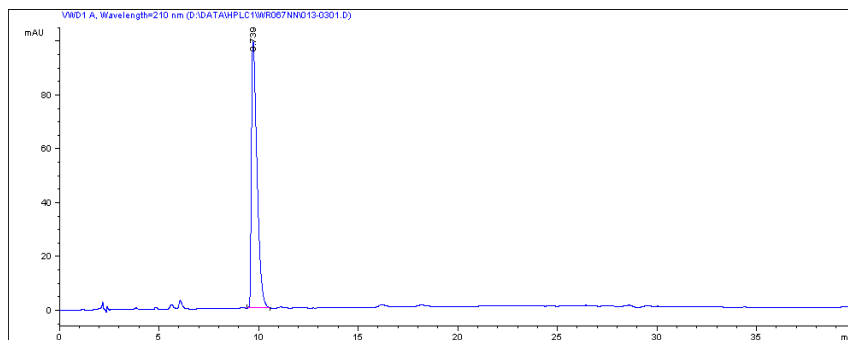
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.067 mol/L ammonium dihydrogen phosphate solution (adjust pH to 7.0 with triethylamine) -acetonitrile (60:40)
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR067NN011-0101.D



The chromatogram of the test solution--- HPLC2WR067NN013-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Roxithromycin	9.74	1931.9	5898	/	1.79



# Roxithromycin Granules – 罗红霉素颗粒

## Roxithromycin (30495-200202) – Method number WR167

### Assay

**Test solution:** Add a quantity of mobile phase to an accurately weighed quantity of the well-mixed contents, treat ultrasonically for 20 minutes, dilute with mobile phase to produce a solution of 0.5 mg of roxithromycin per mL, filter and use the filtrate as the test solution.

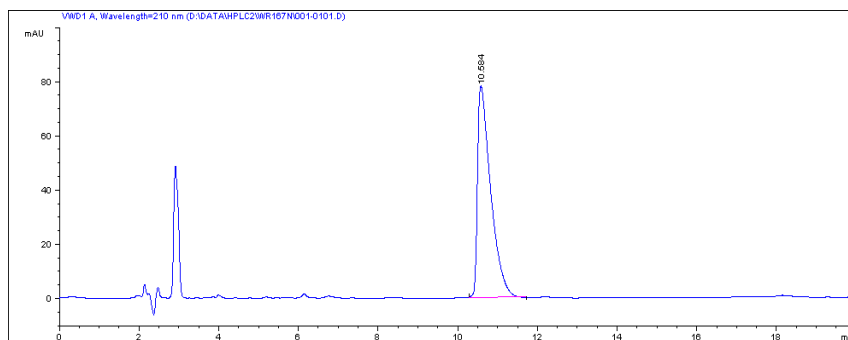
**Reference solution:** Produce the reference solution using roxithromycin CRS, in which the concentration is equivalent to the test solution.

### Chromatographic conditions

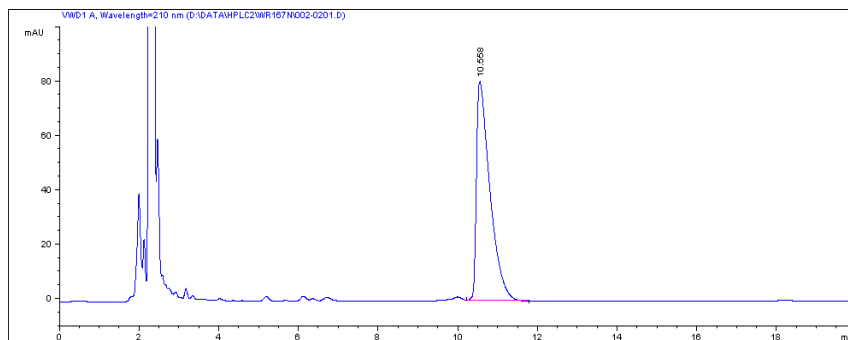
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.067 mol/L ammonium dihydrogen phosphate solution (adjust pH to 7.0 with triethylamine) : acetonitrile = 60 :40
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR167\N001-0101



The chromatogram of the test solution --- HPLC2\WR167\N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Roxithromycin	10.56	1886.4	5128	/	2.38

# Roxithromycin Tablets – 罗红霉素片

Roxithromycin (130351-200303) – Method number WR068

## Assay

Test solution: Accurately weigh 10 tablets and grind to a powder. Dissolve an accurately weighed quantity of powder in mobile phase, treat ultrasonically for 20 minutes, dilute with mobile phase to produce a solution of 1 mg/mL, filter and use the filtrate as the test solution.

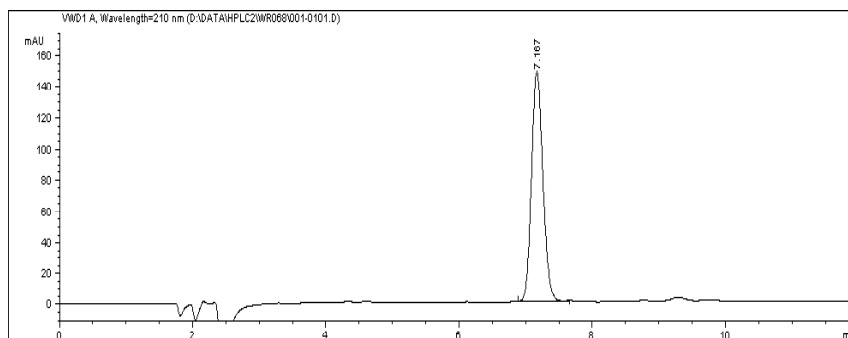
Reference solution: Produce the reference solution using roxithromycin CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

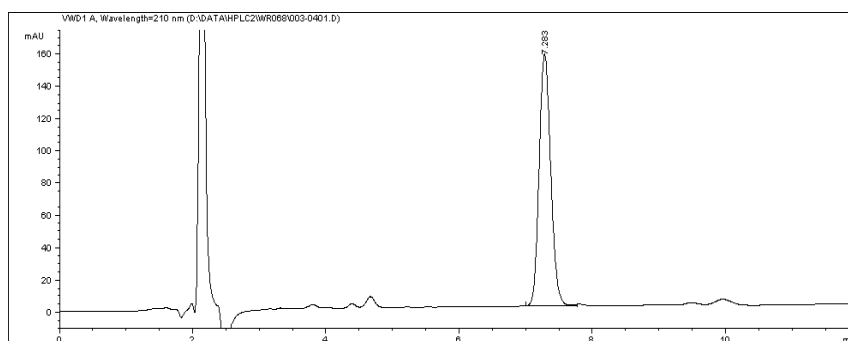
- Column: Intersil ODS3 4.6×250 mm, 5 μm
- Mobile phase: 0.067 mol/L ammonium dihydrogen phosphate solution (adjust pH to 7.0 with triethylamine):acetonitrile = 35:65
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 210 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR068001-0101.D



The chromatogram of the test solution--- HPLC2WR068003-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Roxithromycin	7.28	1905.0	7993	/	1.11

# Enalapril Maleate – 马来酸依那普利

Enalapril maleate, Enalaprilat (011009) Enalapril diketone – Method number WA234

## Assay

Test solution: Dissolve and dilute a quantity of the substance with mobile phase to produce the test solution of 2 mg of enalapril maleate per mL.

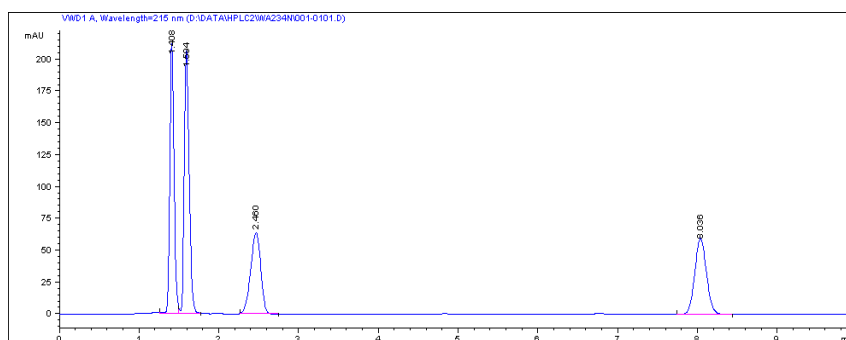
Reference solution: Accurately measure a quantity of the test solution, dilute with mobile phase to produce the reference solution of 40 µg/mL. Dissolve a quantity of enalapril maleate CRS, enalaprilat CRS and enalapril diketone CRS in water to produce a mixed solution of 0.02 mg/mL for the system suitability test.

## Chromatographic conditions

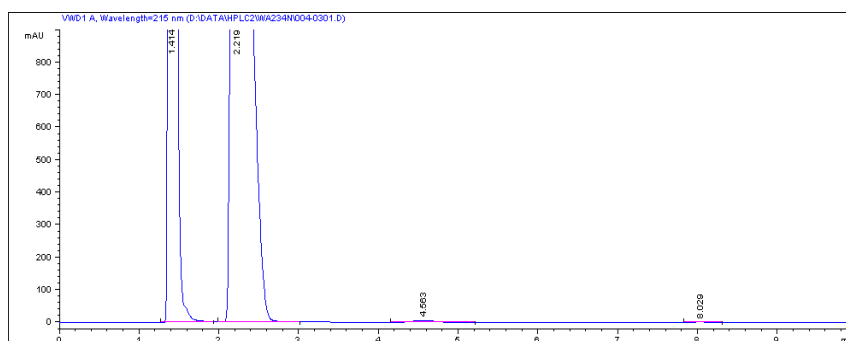
- Column: Agilent ZORBAX XDB C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: acetonitrile:phosphate BS (0.01 mol/L) potassium dihydrogen phosphate solution, adjust pH to 2.2 with phosphoric acid) = 35:65
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 50 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC1WA234N001-0101



The chromatogram of the test solution ---HPLC1WA234N004-0301

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Maleate	1.41	786.8	3448	/	1.15
Enalaprilat	1.59	892.0	2976	1.7	1.19
Enalapril	2.46	565.6	1733	4.9	0.92
Enalapril diketone	8.04	606.8	14523	22.1	1.06

# Enalapril Maleate Capsules – 马来酸依那普利胶囊

Enalapril Maleate – Method number WA236

## Assay

**Test solution:** Accurately weigh a quantity of the contents, equivalent to about 20 mg of enalapril maleate, in a 100 mL volumetric flask, add a quantity of water, treat ultrasonically to dissolve the enalapril maleate, dilute with water to volume, mix well, filter and use the filtrate as the test solution.

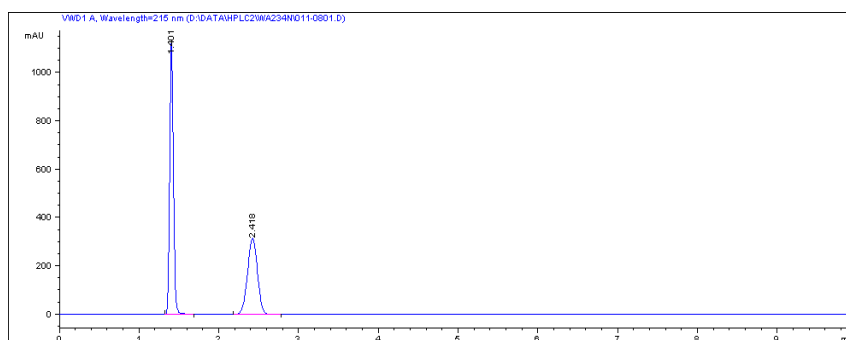
**Reference solution:** Dilute an accurately weighed quantity of enalapril maleate CRS with mobile phase to produce the reference solution of 0.2 mg/mL.

## Chromatographic conditions

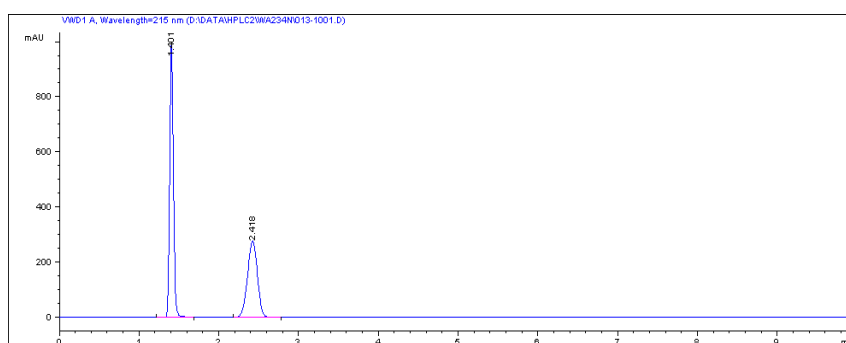
- Column: Agilent ZORBAX XDB C8 4.6×150 mm, 5 µm (993967-906)
- Mobile phase: acetonitrile:phosphate BS (0.01 mol/L) potassium dihydrogen phosphate solution, adjust pH to 2.2 with phosphoric acid) = 35:65
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 50 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA234N011-0801



The chromatogram of the test solution---HPLC1\WA234N013-1001

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Maleate	1.40	3233.4	4628	/	1.13
Enalapril	2.42	2389.2	1713	6.4	0.97

# Enalapril Maleate Capsules – 马来酸依那普利胶囊

Enalapril Maleate – Method number WA236

## Assay

Test solution: Dissolve an accurately weighed quantity of the contents in mobile phase to produce the test solution containing 2 mg/mL.

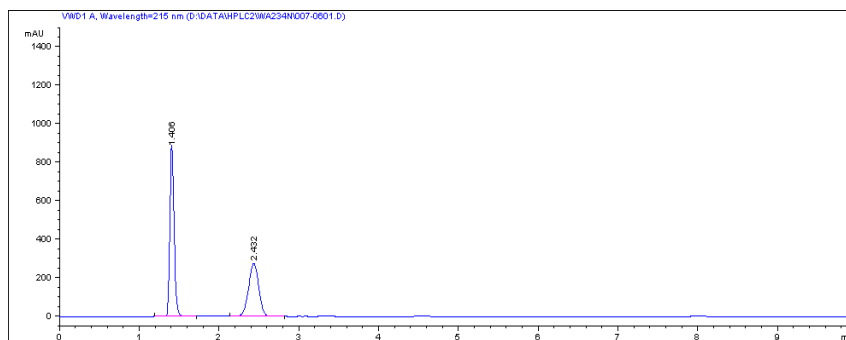
Reference solution: Dissolve an accurately weighed quantity of the contents in mobile phase to produce the reference solution containing 0.1 mg/mL.

## Chromatographic conditions

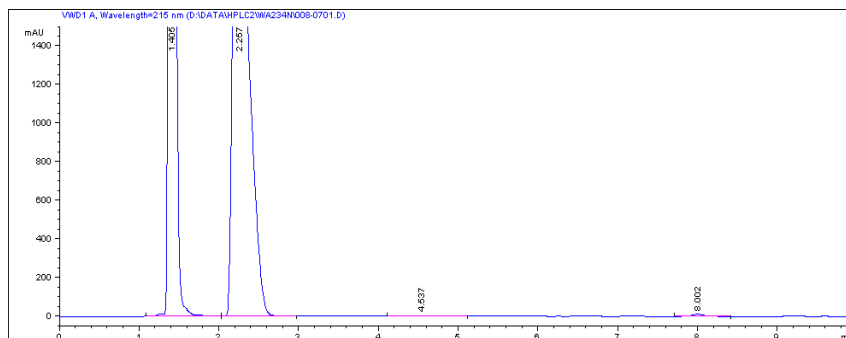
- Column: Agilent ZORBAX XDB C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: acetonitrile:phosphate BS (0.01 mol/L) potassium dihydrogen phosphate solution, adjust pH to 2.2 with phosphoric acid) = 35:65
- Flow rate: 1.0 mL/ min I
- Injection volume: 10 µL
- Column temperature: 50 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA234N007-0601



The chromatogram of the test solution---HPLC1\WA234N008-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	R	USP T <sub>r</sub>
Maleate	1.41	25312.1	1053	/	1.27
Enalapril	2.26	36360.4	592	3.1	1.56
Impurity	4.54	92.9	1239	5.1	0.94
Enalapril diketone	8.00	112.2	13830	8.8	1.06

# Enalapril Maleate Tablets – 马来酸依那普利片

Enalapril Maleate – Method number WA235

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 20 mg of enalapril maleate, in a 100 mL volumetric flask, add a quantity of water, treat ultrasonically to dissolve the enalapril maleate, dilute with water to volume, mix well, filter and use the filtrate as the test solution.

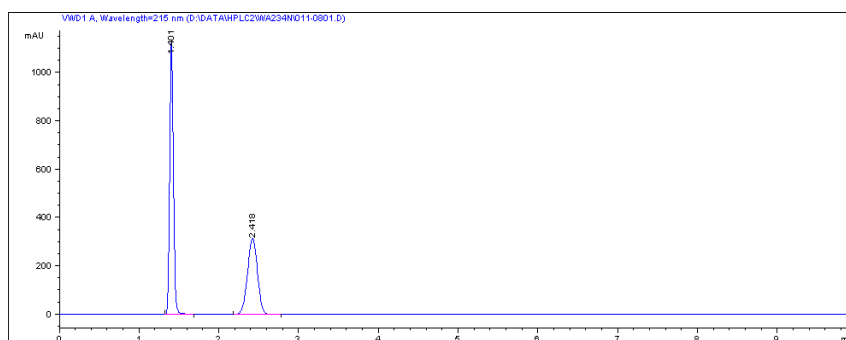
Reference solution: Dilute an accurately weighed quantity of enalapril maleate CRS with mobile phase to produce the reference solution containing 0.2 mg/mL.

## Chromatographic conditions

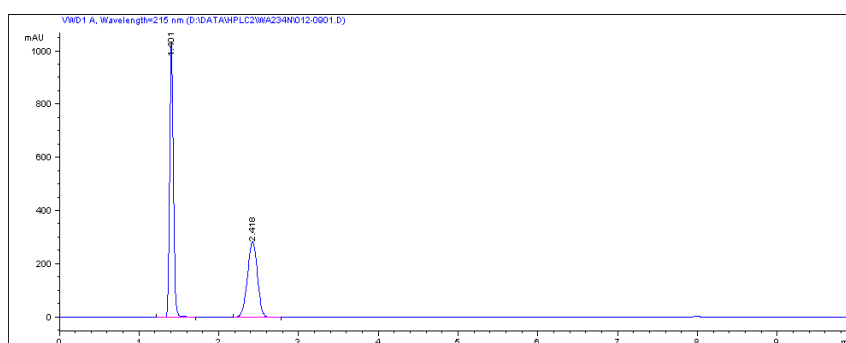
- Column: Agilent ZORBAX XDB C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: acetonitrile:phosphate BS (0.01 mol/L) potassium dihydrogen phosphate solution, adjust pH to 2.2 with phosphoric acid) = 35:65
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 50 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA234N011-0801



The chromatogram of the test solution ---HPLC1WA234N012-0901

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Maleate	1.40	3345.7	4394	/	1.14
Enalapril	2.42	2476.2	1712	6.4	0.97

# Enalapril Maleate Tablets – 马来酸依那普利片

Enalapril Maleate – Method number WA235

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder and dissolve in mobile phase to produce the test solution containing 2 mg/mL.

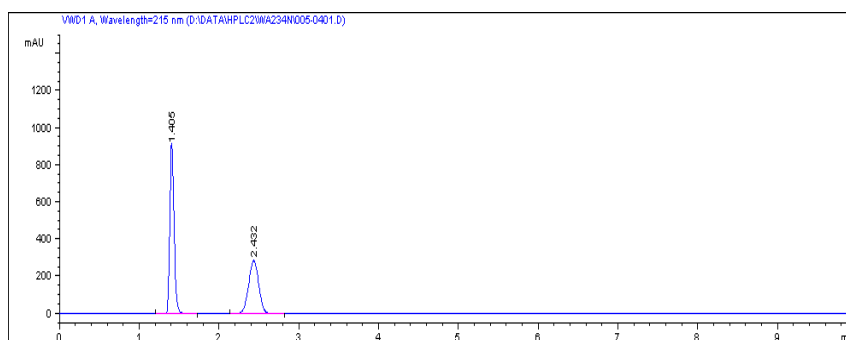
Reference solution: Repeat the procedure to produce the reference solution containing 0.1 mg/mL.

## Chromatographic conditions

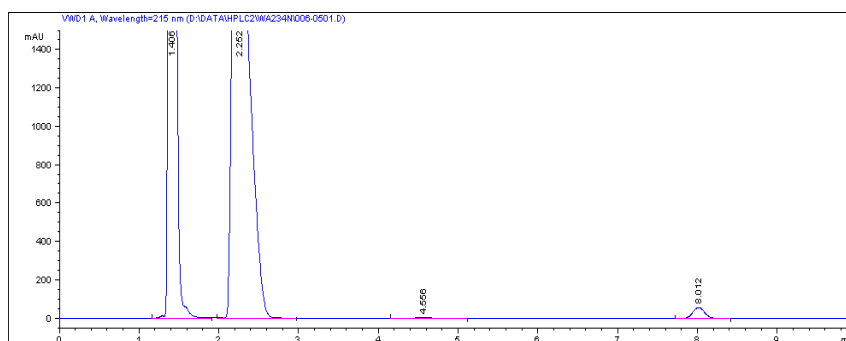
- Column: Agilent ZORBAX XDB C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: acetonitrile:phosphate BS (0.01 mol/L) potassium dihydrogen phosphate solution, adjust pH to 2.2 with phosphoric acid) = 35:65
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 50 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA234N005-0401



The chromatogram of the test solution---HPLC1\WA234N006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Maleate	1.41	25983.4	1032	/	1.16
Enalapril	2.25	38213.4	518	2.9	1.58
Impurity	4.56	85.5	1250	5.0	0.90
Enalapril diketone	8.01	592.6	14147	8.8	1.05

# Moclobemide – 吗氯贝胺

Moclobemide (100583-200401) – Method number WA260

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution of 1.5 mg/mL.

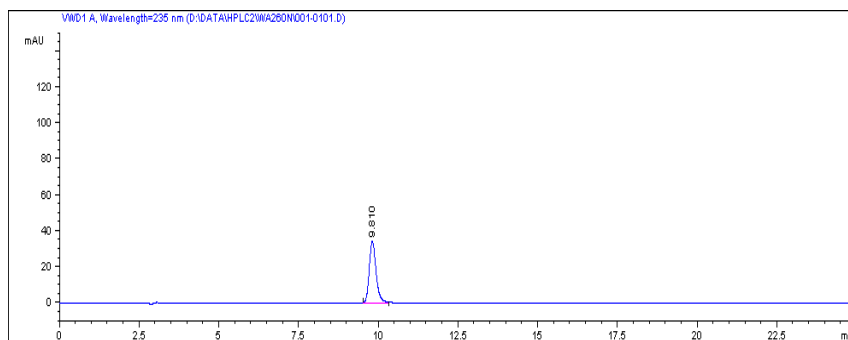
Reference solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the reference solution of 15 µg/mL.

## Chromatographic conditions

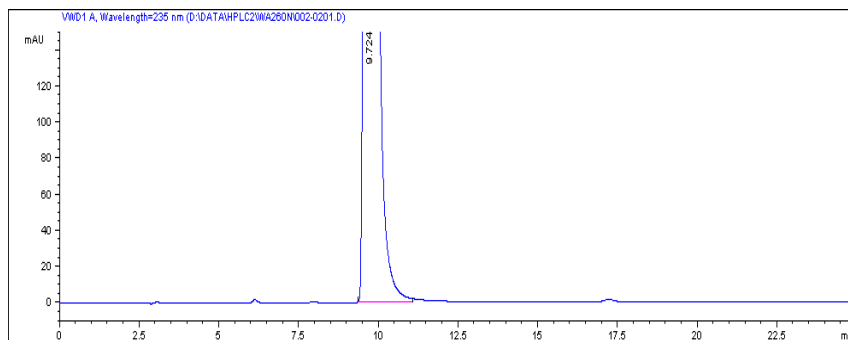
- Column: Agilent ZORBAX XDB-CN 4.6×250 mm, 5 µm (990967-905)
- Mobile phase: methanol:0.14 % triethylamine solution (adjust pH to 6.0 with phosphoric acid) = 30:70
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 235 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA260N001-0101



The chromatogram of the test solution--- HPLC2WA260N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Moclobemide	9.73	51050.0	8237	/	1.18



# Meleumycin – 麦白霉素

Midecamycin (130526-200201) Meleumycin (341-9402) – Method number WA089

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase, dilute to volume to produce the test solution of about 2 mg/mL.

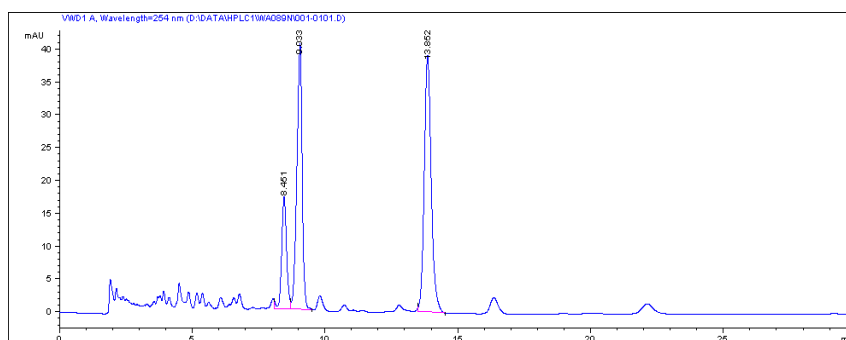
Reference solution: Repeat the procedure using meleumycin CRS with a known content of midecamycin A1 to produce the reference solution.

## Chromatographic conditions

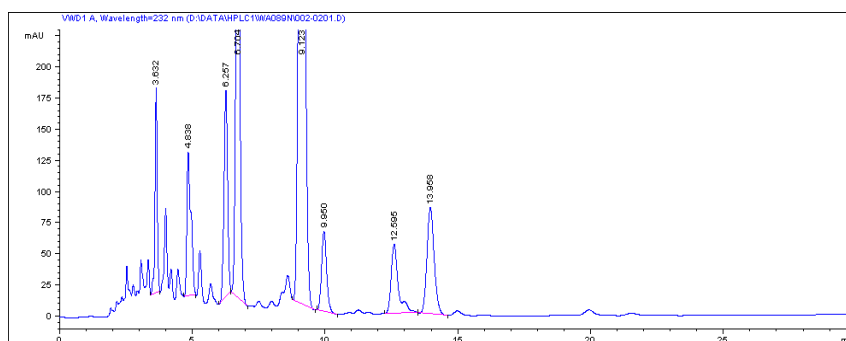
- Column: Agilent ZORBAX XDB C18 4.6×250mm, 5 µm (990967-902)
- Mobile phase: 0.2 mol/L ammonium formate (adjust to pH 7.3 with triethylamine) : acetonitrile = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 232nm (meleumycin)  
254nm (midecamycin)

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of Midecamycin---HPLC1\WA089N001-0101



The chromatogram of the test solution --- HPLC1\ WA089N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Midecamycin A1	9.12	13750.5	12871	/	1.01

# Meleumycin Tablets – 麦白霉素片

Midecamycin (130526-200201) Meleumycin (341-9402) – Method number WA264

## Assay

Test solution: Dissolve an accurately weighed quantity of the powder in mobile phase to produce the test solution of about 2 mg/mL.

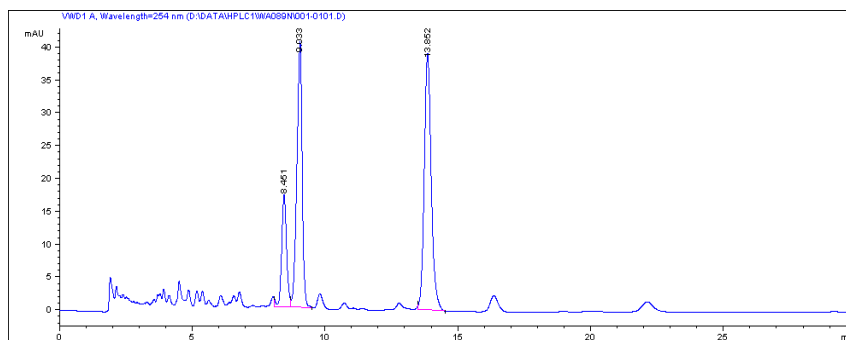
Reference solution: Repeat the procedure using meleumycin CRS with a known content of midecamycin A1 to produce the reference solution.

## Chromatographic conditions

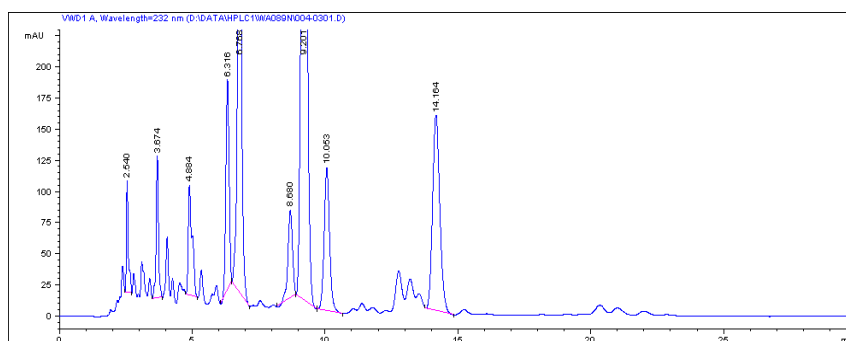
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.2 mol/L ammonium formate (adjust pH to 7.3 with triethylamine) : acetonitrile = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 232 nm (meleumycin)  
254 nm (midecamycin)

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of midecamycin---HPLC1\WA089N001-0101



The chromatogram of the test solution --- HPLC1\WA089N004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Midecamycin A1	9.20	10778.3	13317	/	1.04

# Meropenem – 美罗培南

Meropenem(130506-200401) – Method number WA288

## Assay

Test solution: Dissolve an accurately weighed quantity in mobile phase to produce the test solution of 5 mg/mL.

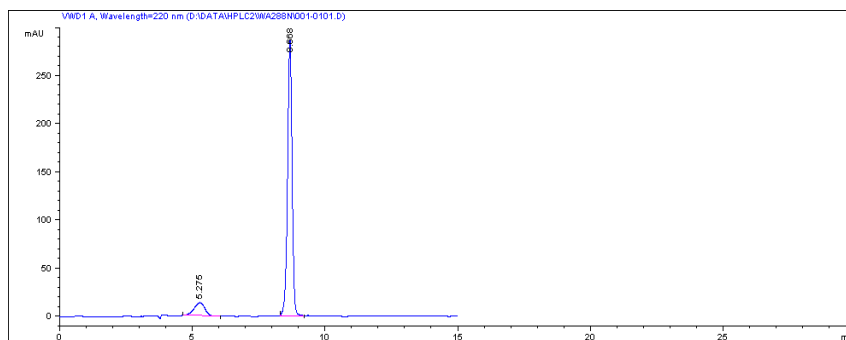
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 25 µg/mL. Heat a quantity of the solution of meropenem CRS in a water bath for 1 hour and use for the system suitability test.

## Chromatographic conditions

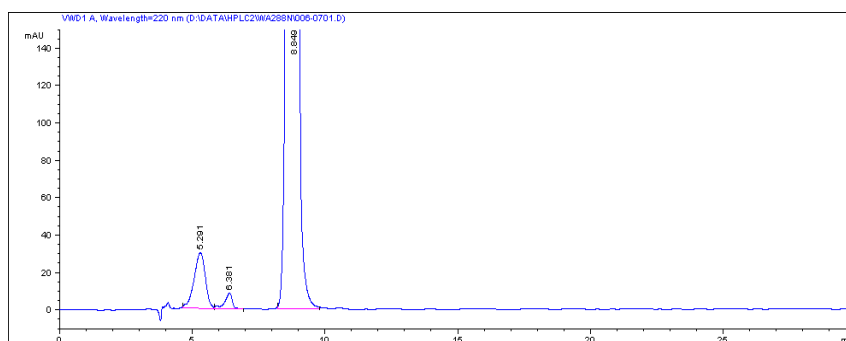
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.3 % triethylamine solution (measure 3.0 mL of triethylamine in 900 mL water, adjust pH to 5.0 with phosphoric acid, dilute with water to 1000 mL):acetonitrile = 93:7
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability---HPLC2\WA288N001-0101



The chromatogram of the test solution--- HPLC2\WA288N006-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Meropenem	8.85	68178.9	5382	5.2	0.77
Degradation Product	5.29	889.8	753	/	0.85
Impurity	6.38	166.3	3053	1.8	/

# Meloxicam – 美洛昔康

Meloxicam (100679-200401) – Method number WA132

## Assay

Test solution: Dissolve an accurately weighed quantity in mobile phase to produce the test solution of 1 mg/mL.

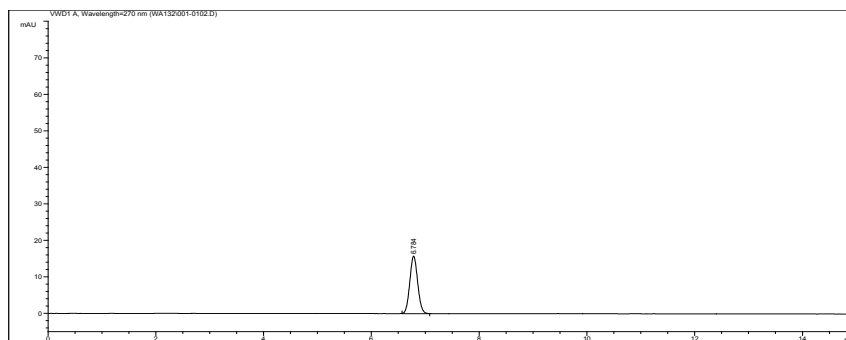
Reference solution: Dilute an accurately measured volume of the test solution with mobile phase to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

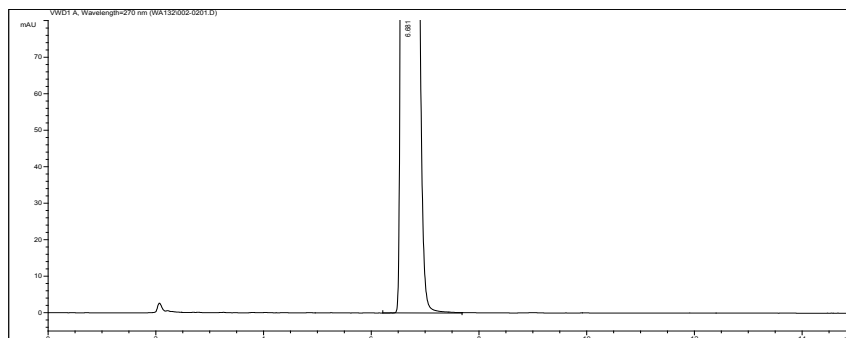
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase : methanol : 0.1 mol/L ammonium acetate = 1:1
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 270 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA132\001-0102



The chromatogram of the test solution--- HPLC1\ WA132\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Meloxicam	6.68	14980.0	4117	/	1.32

# Compound Miconazole Nitrate Cream – 咪康唑氯倍他索乳膏

Miconazole nitrate (10213-9903)

Clobetasol propionate (10302-0001) – Method number WA276

## Assay

Internal standard solution: Measure 0.4 mL of dibutyl phthalate in a 100 mL volumetric flask, dilute with methanol to volume, mix well and use as internal standard solution.

Test solution: Accurately weigh about 2.5 g in a beaker, accurately add 1 mL of internal standard solution. Add 20 mL of methanol, heat in a water bath at 80 °C, stirring occasionally until the cream is completely dissolved, cool on an ice-water bath until the base is completely frozen, filter and extract with 15 and 10 ml of methanol, combine the filtrate and washings in a 50 ml volumetric flask, add methanol to volume and mix well. Freeze for 2 hours, filter immediately and use the filtrate as the test solution.

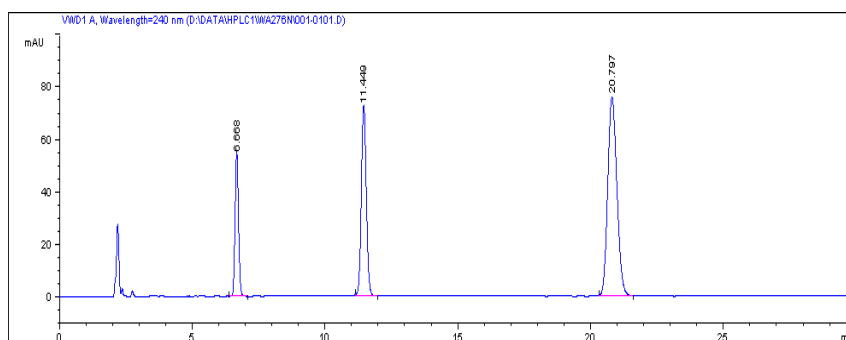
Reference solution: Produce a reference solution of 1 mg of miconazole nitrate and 25 µg of clobetasol propionate per mL using miconazole nitrate CRS and clobetasol propionate CRS.

## Chromatographic conditions

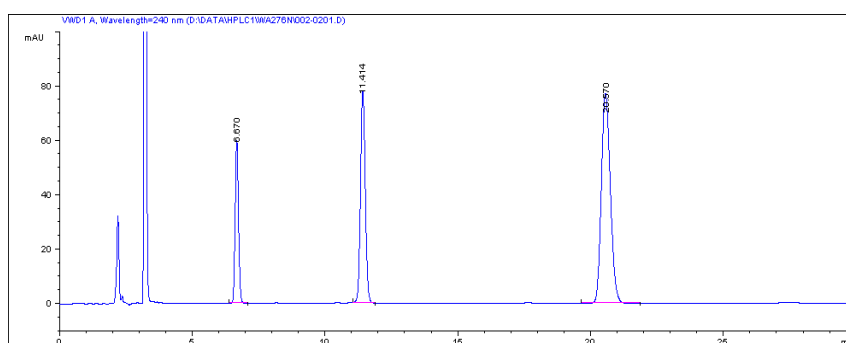
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.5 % ammonium acetate solution: acetonitrile: methanol = 24:38:38
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 35 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA276N001-0101



The chromatogram of the test solution --- HPLC1WA276N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clobetasol Propionate	6.67	521.8	13346	/	1.08
Dibutyl Phthalate	11.41	980.3	19152	16.9	1.06
Miconazole Nitrate	20.57	1821.0	15550	18.5	1.09

# Naproxen and Codeine Phosphate Tablets – 萘普待因片

Naproxen (100198-0002) Codeine phosphate (171203-200303) – Method number WA195

## Assay

**Test solution:** Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of powder, equivalent to about 150 mg naproxen and 15 mg codeine phosphate respectively, in a 50 mL volumetric flask, add a quantity of 75 % methanol solution, treat ultrasonically for 10 minutes, dilute with 75 % methanol solution to volume, shake thoroughly and filter. Accurately measure 3 mL of the filtrate in a 10 mL volumetric flask, dilute with 75 % methanol solution to volume, mix well and use as the test solution.

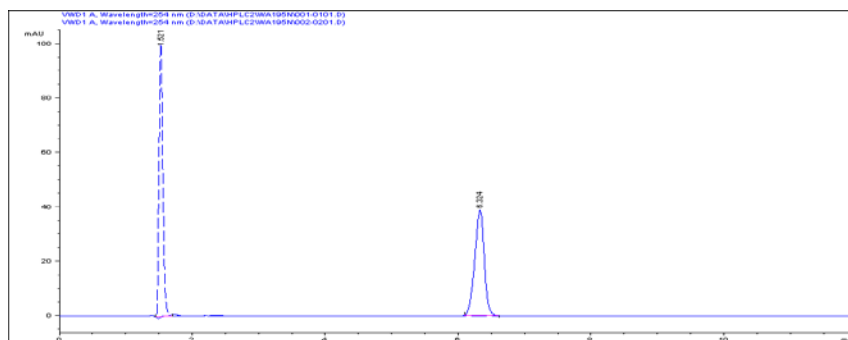
**Reference solution:** Dissolve an accurately weighed quantity of naproxen CRS and codeine phosphate CRS in 75 % methanol solution to produce the reference solution of 0.9 mg naproxen and 0.09 mg codeine phosphate per mL.

## Chromatographic conditions

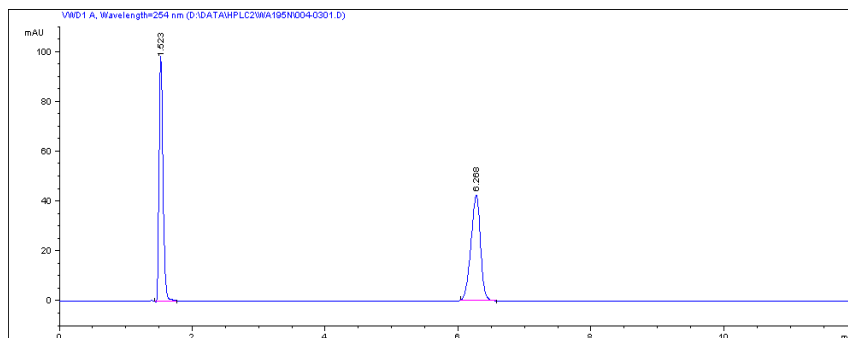
- Column: Agilent ZORBAX Eclipse XDB C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate: methanol:tetrahydrofuran = 45:55:0.4
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA195001-0101 002-0201



The chromatogram of the test solution ---HPLC2WA195004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Codeine Phosphate	1.52	407.5	3229	/	1.24
Naproxen	6.26	423.6	8301	24.8	0.95

# Naproxen – 萘普生

Naproxen (10163-0004) – Method number WR104

## Assay

Test solution: Protect from light throughout the procedure. Dissolve an accurately weighed quantity in the mobile phase, shake thoroughly to dissolve naproxen and dilute to produce the test solution of 500 µg/mL.

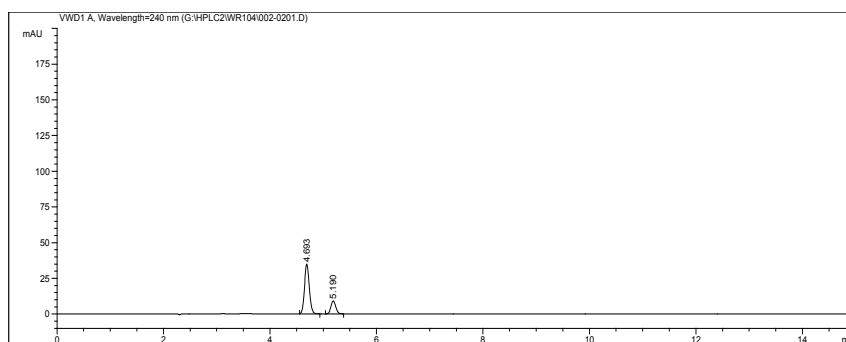
Reference solution: Dissolve a quantity of 6-methoxy-2-acetonaphthone CRS in the mobile phase and dilute to produce a reference solution of the known impurity of 50 µg/mL. Accurately measured 1 mL of test solution and 2 mL of the reference solution of the impurity in a 200 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution, containing 2.5 µg naproxen and 0.5 µg 6-methoxy-2-acetonaphthone per mL.

## Chromatographic conditions

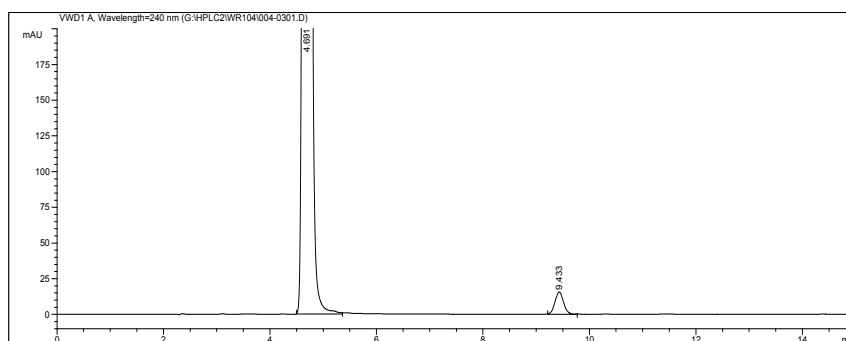
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol-0.01 mol/L potassium dihydrogen phosphate solution (75:25) (adjust pH to 3.0 with phosphoric acid)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR104\002-0201.D



The chromatogram of the test solution --- HPLC1\WR100\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Naproxen	4.69	220.2	13277	/	1.06
2-Acetyl-6-methoxynaphthalene	5.19	57.6	16237	3.0	1.05

# Naproxen Capsules – 萘普生胶囊

## Naproxen (10198-0002) – Method number WR107

### Assay

Test solution: Protect from light throughout the procedure. Accurately weigh a quantity of the contents, equivalent to about 25 mg of naproxen, in a 50 mL volumetric flask, add a quantity of mobile phase, shake thoroughly to dissolve the naproxen, dilute to volume, mix well, filter and use the filtrate as the test solution.

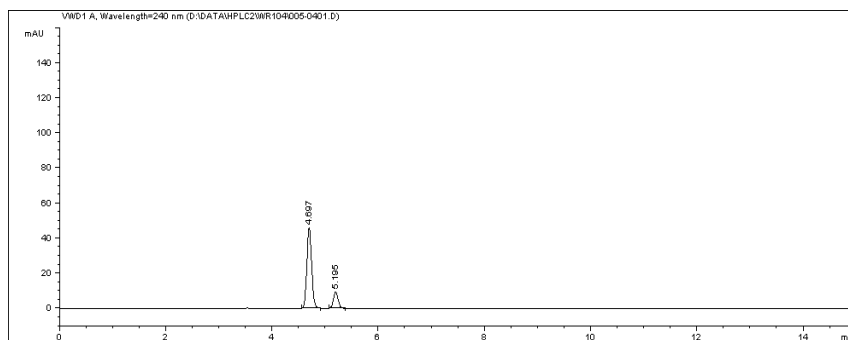
Reference solution: Dissolve a quantity of 6-methoxy-2-acetonaphthone CRS in mobile phase to produce a reference solution of the known impurity of 50 µg/mL. Accurately measure 1 mL each of the test solution and of the reference solution of the impurity in a 100 mL volumetric flask and dilute with mobile phase to volume, mix well and use as the reference solution.

### Chromatographic conditions

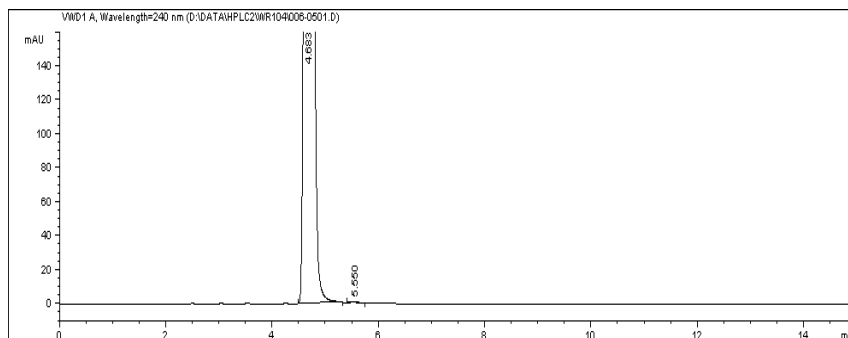
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol-0.01 mol/L potassium dihydrogen phosphate solution (75:25)(adjust pH to 3.0 with phosphoric acid)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR104005-0401



The chromatogram of the test solution--- HPLC2WR104006-0501

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Naproxen	4.68	16537.1	7439	/	1.09
2-Acetyl-6-methoxynaphthalene	5.55	6.8	12842	4.2	0.87



# Naproxen Granules – 萘普生颗粒

## Naproxen (10163-0004) – Method number WR108

### Assay

**Test solution:** Protect from light throughout the procedure. Accurately weigh a quantity of the powdered granules, equivalent to about 25 mg of naproxen, in a 50 mL volumetric flask, add a quantity of mobile phase, shake thoroughly to dissolve the naproxen, dilute to volume, mix well, filter and use the filtrate as the test solution, containing 500 µg/mL.

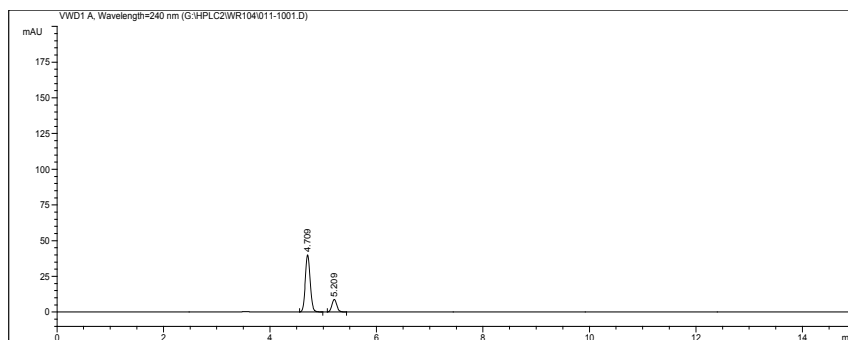
**Reference solution:** Dissolve a quantity of 6-methoxy-2-acetonaphthone CRS in mobile phase to produce a reference solution of the known impurity of 50 µg/mL. Accurately measure 1 mL each of test solution and of the reference solution of the impurity in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution, containing 5 mg naproxen and 0.5 mg 6-methoxy-2-acetonaphthone CRS per mL.

### Chromatographic conditions

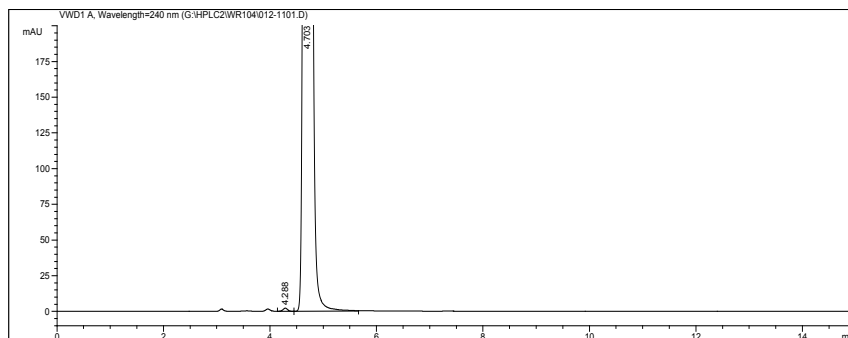
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol-0.01 mol/L potassium dihydrogen phosphate solution (75:25) (adjust pH to 3.0 with phosphoric acid)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR104011-1001.D



The chromatogram of the test solution --- HPLC2WR104012-1101.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Naproxen	4.70	17068.4	7898	2.3	1.11
2-Acetyl-6-methoxynaphthalene	5.21	/	/	/	/
Impurity	4.29	12.7	12250		1.05

# Naproxen Tablets – 萘普生片

Naproxen (10198-0002) – Method number WR105

## Assay

Test solution: Protect from light throughout the procedure. Accurately weigh a quantity of the powdered tablets, equivalent to about 25 mg of naproxen, in a 50 mL volumetric flask, add a quantity of mobile phase, shake thoroughly to dissolve the naproxen, dilute to volume, mix well, filter and use the filtrate as the test solution, containing 500 µg/mL.

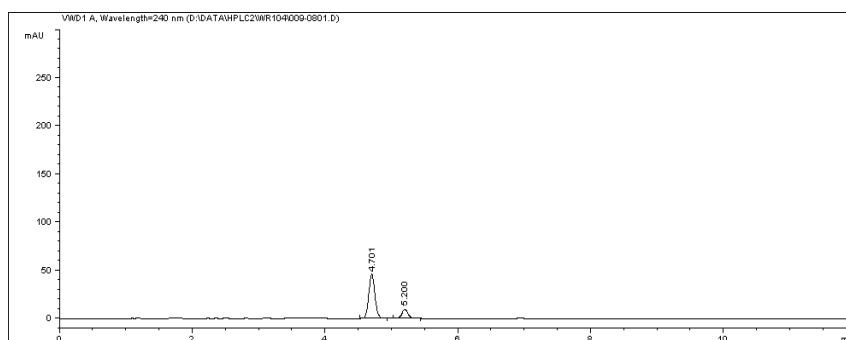
Reference solution: Dissolve a quantity of 6-methoxy-2-acetonaphthone CRS in mobile phase to produce a reference solution of the known impurity of 50 µg/mL. Accurately measure 1 mL each of test solution and of the reference solution of the impurity in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution, containing 5 mg naproxen and 0.5 mg 6-methoxy-2-acetonaphthone CRS per mL.

## Chromatographic conditions

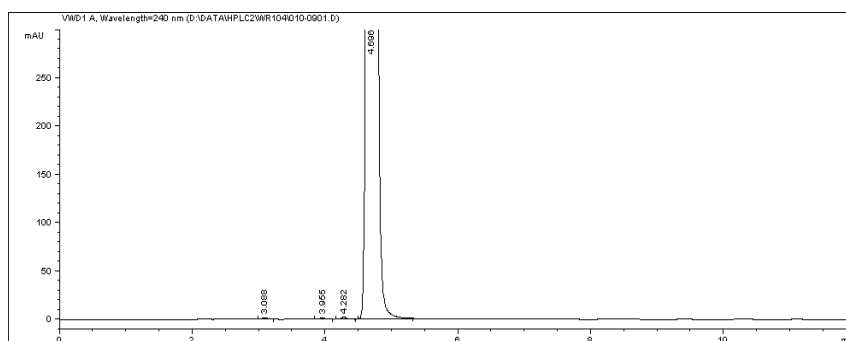
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol-0.01 mol/L potassium dihydrogen phosphate solution (75:25) (adjust pH to 3.0 with phosphoric acid)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR104009-0801



The chromatogram of the test solution--- HPLC2WR104010-0901

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Naproxen	4.70	17089.9	7672	2.2	1.12
Impurity1	3.09	8.8	8764	/	1.05
Impurity2	3.96	8.7	12153	6.3	1.12
Impurity3	4.28	12.8	12465	2.2	1.04

# Naproxen Suppositories – 萘普生栓

Naproxen (10163-0004) – Method number WR106

## Assay

Test solution: Protect from light throughout the procedure. Accurately weigh a quantity of the substance, equivalent to about 50 mg of naproxen, in a 50ml volumetric flask, melt by warming on a water bath, cool to room temperature, dilute with methanol to volume, heat on a water bath at 50-60 °C and shake well. Allow to stand for 10 minutes and cool to room temperature. After freezing in refrigerator (-18 °C) for 1 hour, filter immediately, discard the initial filtrate and cool to room temperature. Accurately measure 25 mL of the successive filtrate in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well, filter and use the filtrate as the test solution.

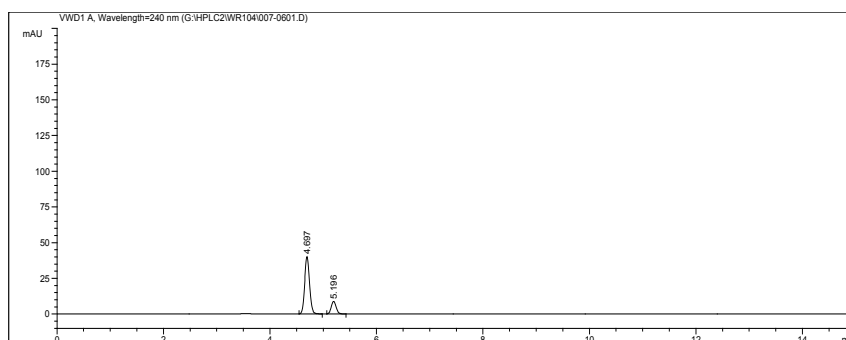
Reference solution: Dissolve a quantity of 6-methoxy-2-acetonaphthone CRS in mobile phase to produce a reference solution of the known impurity of 50 µg/mL. Accurately measure 1 mL each of test solution and of the reference solution of the impurity in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution, containing 5 mg naproxen and 0.5 mg 6-methoxy-2-acetonaphthone CRS per mL.

## Chromatographic conditions

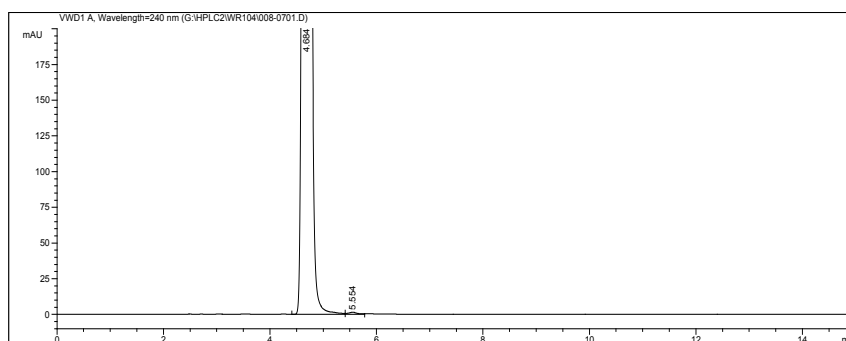
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol-0.01 mol/L potassium dihydrogen phosphate solution (75:25) (adjust pH to 3.0 with phosphoric acid)
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 240 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR104007-0601.D



The chromatogram of the test solution--- HPLC2WR104008-0701.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Naproxen	4.69	16532.1	7357		1.07
2-Acetyl-6-methoxynaphthalene	5.55	7.0	12087	4.1	0.85

# Nimodipine – 尼莫地平

Nimodipine (10270-0002) – Method number WA245

## Assay

Test solution: Dissolve an accurately weighed quantity in mobile phase to produce the test solution of 0.2 mg/mL.

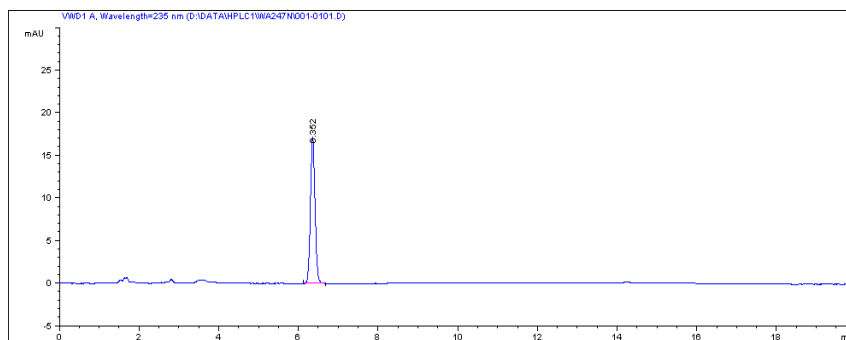
Reference solution: Dissolve an accurately weighed quantity in mobile phase to produce the reference solution of 2 µg/mL.

## Chromatographic conditions

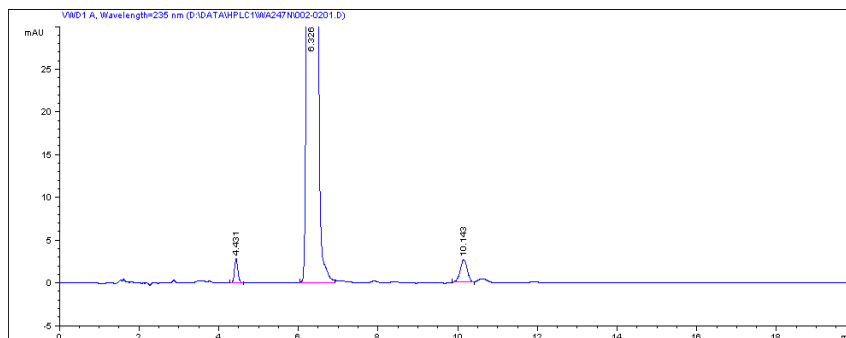
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile : water = 35: 38:27
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 235 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA247N001-0101



The chromatogram of the test solution-- HPLC1\WA247N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Nimodipine	6.33	13833.7	15058	10.5	1.06
Impurity1	4.43	16.5	13492	/	1.08
Impurity2	10.14	32.4	16323	14.6	0.96

# Nimodipine Dispersible Tablets – 尼莫地平分散片

Nimodipine (10270-0002) – Method number WA247

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 10 mg of nimodipine, in a 50 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolve the nimodipine, dilute to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

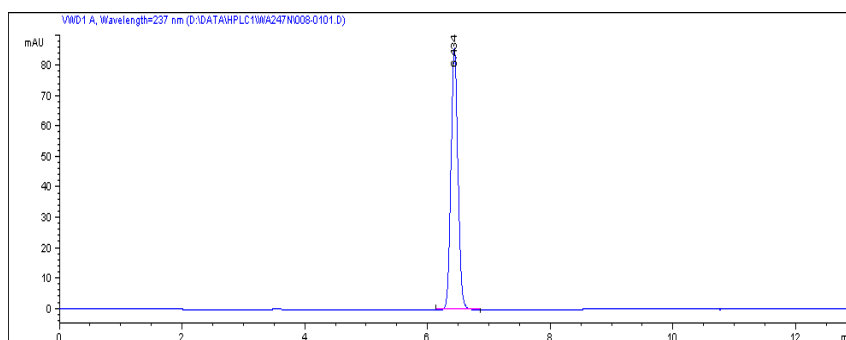
Reference solution: Dissolve an accurately weighed quantity of nimodipine CRS in mobile phase to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

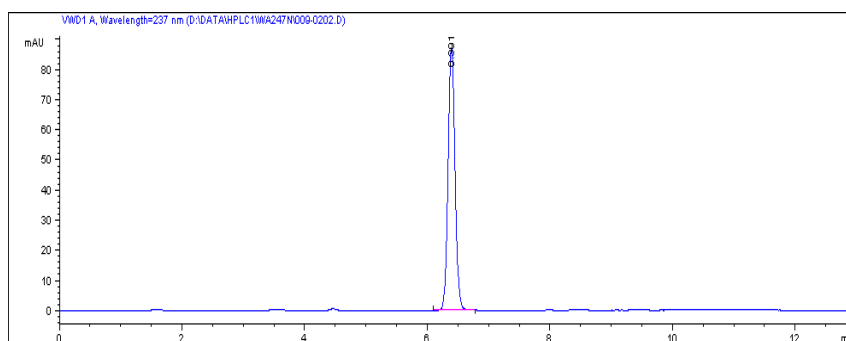
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water = 35:38:27
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 237 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1WA247N008-0101



The chromatogram of the test solution--- HPLC1WA247N009-0202

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nimodipine	6.39	687.6	14970	/	1.05

# Nimodipine Dispersible Tablets – 尼莫地平分散片

Nimodipine (10270-0002) – Method number WA247

## Assay

**Test solution:** Accurately weigh a quantity of the powder, equivalent to about 10 mg of nimodipine, in a 50 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolved the nimodipine, dilute to volume, mix well, filter and use the filtrate as the test solution.

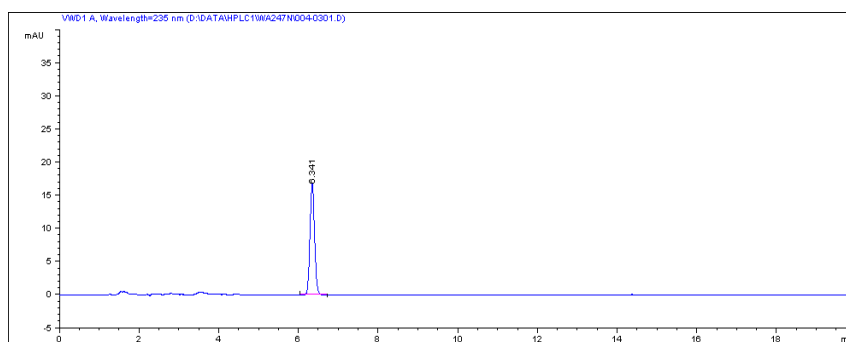
**Reference solution:** Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 2 µg/mL.

## Chromatographic conditions

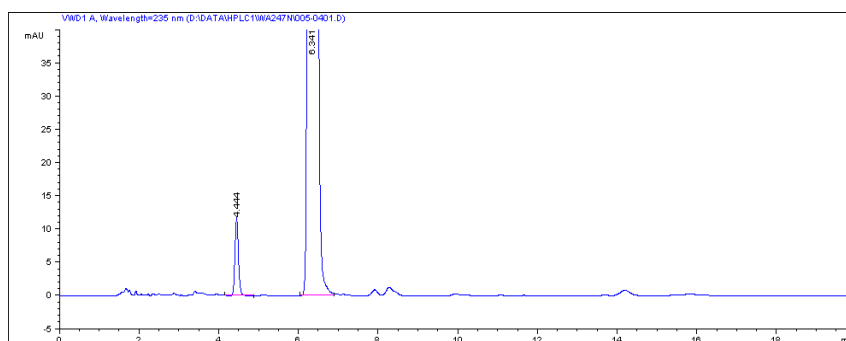
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water = 35:38:27
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 235 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA247N004-0301



The chromatogram of the test solution--- HPLC1\WA247N005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Nimodipine	6.34	13912.2	14736	10.4	1.06
Impurity	4.44	69.6	12867	/	1.07

# Nimodipine Capsules – 尼莫地平胶囊

Nimodipine (10270-0002) – Method number WA249

## Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 10 mg of nimodipine, in a 50 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolve the nimodipine, dilute to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

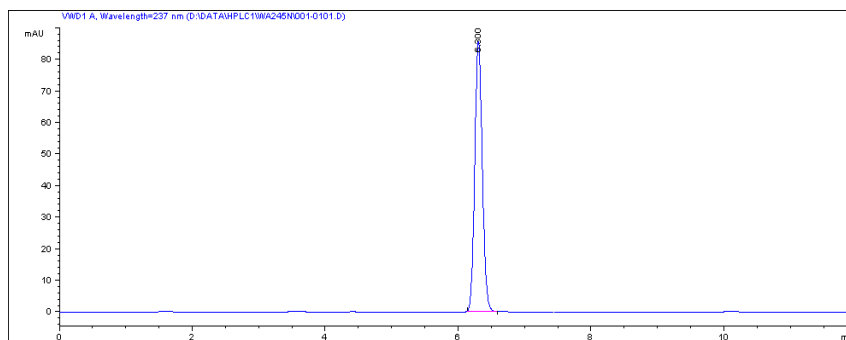
Reference solution: Dissolve an accurately weighed quantity of nimodipine CRS in mobile phase to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

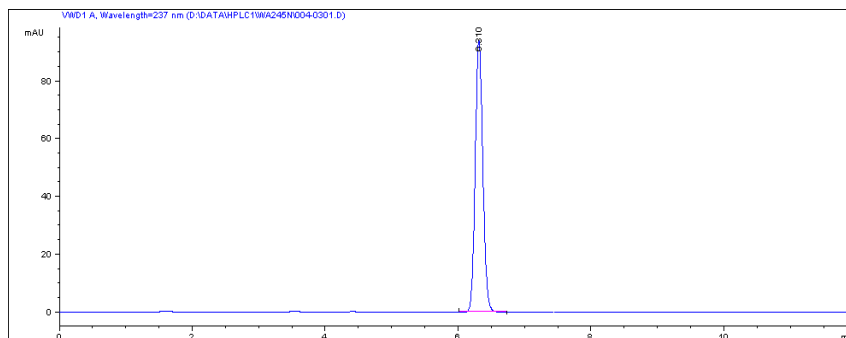
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water= 35:38:27
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 237 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA245N001-0101



The chromatogram of the test solution--- HPLC1\WA245N004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nimodipine	6.31	753.3	14593	/	1.08

# Nimodipine Capsules – 尼莫地平胶囊

Nimodipine (10270-0002) – Method number WA249

## Assay

**Test solution:** Accurately weigh a quantity of the well-mixed contents, equivalent to about 10 mg of nimodipine, in a 50 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolve the nimodipine, dilute to volume, mix well, filter and use the filtrate as the test solution.

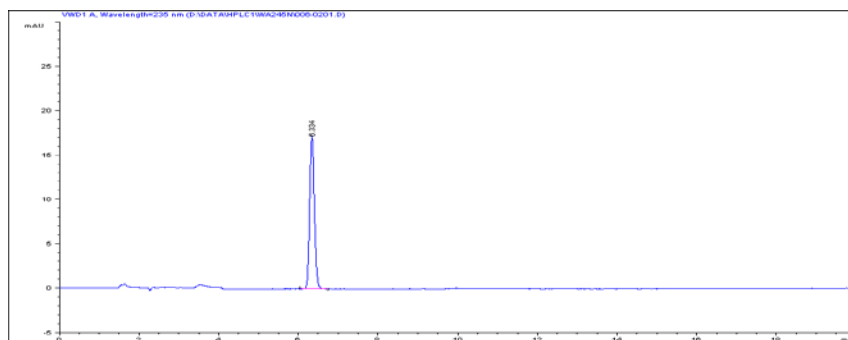
**Reference solution:** Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 2 µg/mL.

## Chromatographic conditions

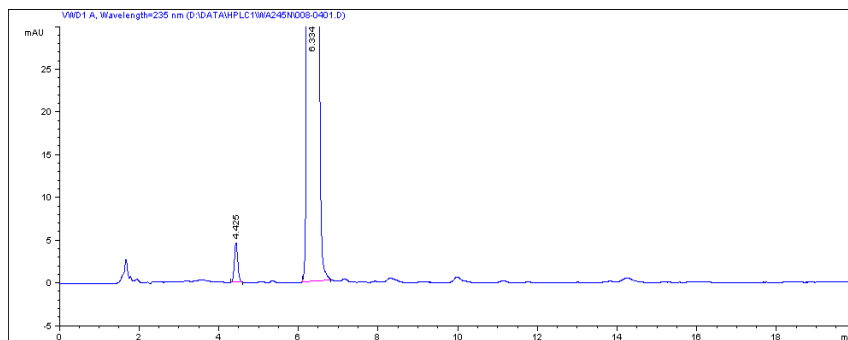
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water = 35:38:27
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 235 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA245N\006-0201



The chromatogram of the test solution--- HPLC1\WA245N\008-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nimodipine	6.34	15105.1	13973	10.2	1.09
Impurity	4.43	28.0	12438	/	1.10



# Nimodipine Tablets – 尼莫地平片

Nimodipine (10270-0002) – Method number WA246

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 10 mg of nimodipine, in a 50 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolve the nimodipine, dilute to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

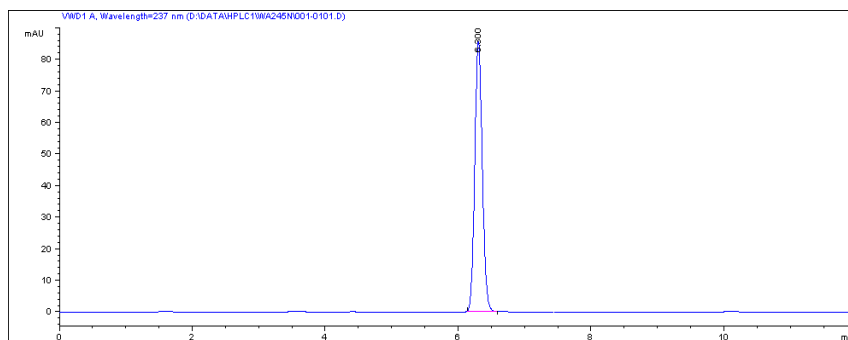
Reference solution: Dissolve an accurately weighed quantity of nimodipine CRS in mobile phase to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

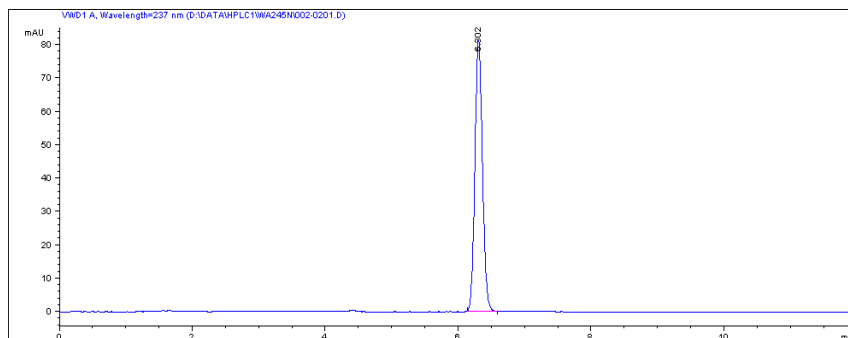
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water = 35:38:27
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 237 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA245N001-0101



The chromatogram of the test solution--- HPLC1\WA245N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nimodipine	6.31	648.1	14570	/	1.08

# Nimodipine Tablets – 尼莫地平片

## Nimodipine (10270-0002) – Method number WA246

### Assay

Test solution: Accurately weigh a quantity of the powder, equivalent to about 10 mg of nimodipine, in a 50 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolved the nimodipine, dilute to volume, mix well, filter and use the filtrate as the test solution.

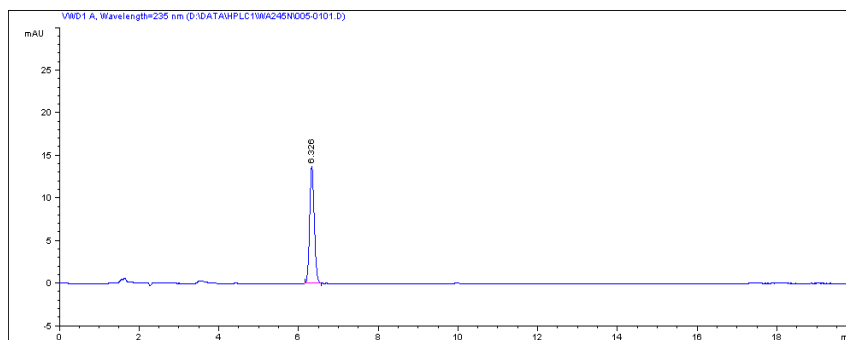
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 2 µg/mL.

### Chromatographic conditions

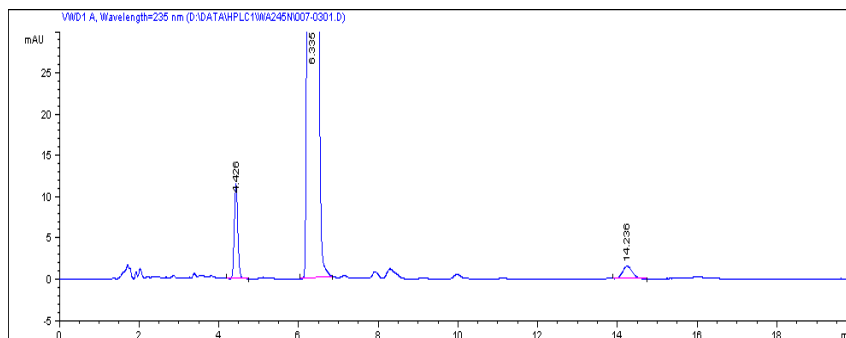
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water = 35:38:27
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 235 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA245N005-0101



The chromatogram of the test solution-- HPLC1\WA245N007-0301

Constituents (Test solution)	Ret Time ( min )	Area (mAU*s)	N	Rs	USP Tf
Nimodipine	6.34	13851.5	13272	9.7	1.08
Impurity1	4.43	69.6	10447	/	1.09
Impurity2	14.24	27.3	15476	23.3	1.10

# Nimodipine Injection – 尼莫地平注射液

Nimodipine (10270-0002) – Method number WA248

## Assay

Test solution: Accurately measure 5 mL of the injection fluid in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

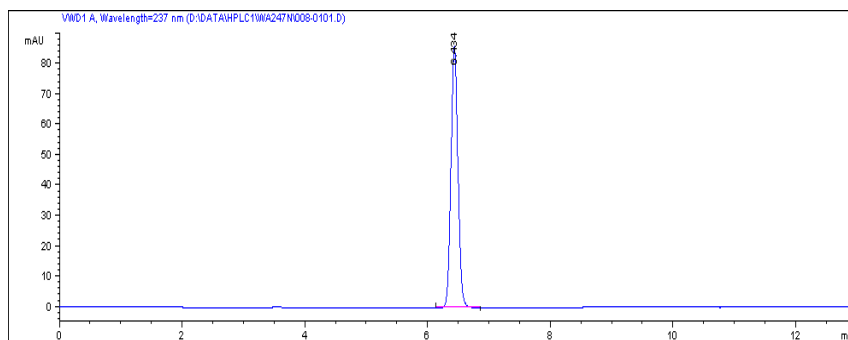
Reference solution: Dissolve an accurately weighed quantity of nimodipine CRS in mobile phase to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

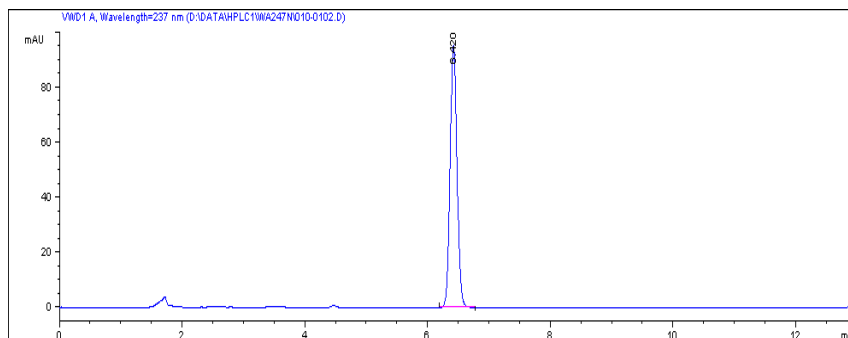
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water = 35:38:27
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 237 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1WA247N008-0101



The chromatogram of the test solution--- HPLC1WA247N010-0102

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nimodipine	6.42	753.2	14714	/	1.05

# Nimodipine Injection – 尼莫地平注射液

Nimodipine (10270-0002) – Method number WA248

## Assay

Test solution: Use the injection fluid as the test solution.

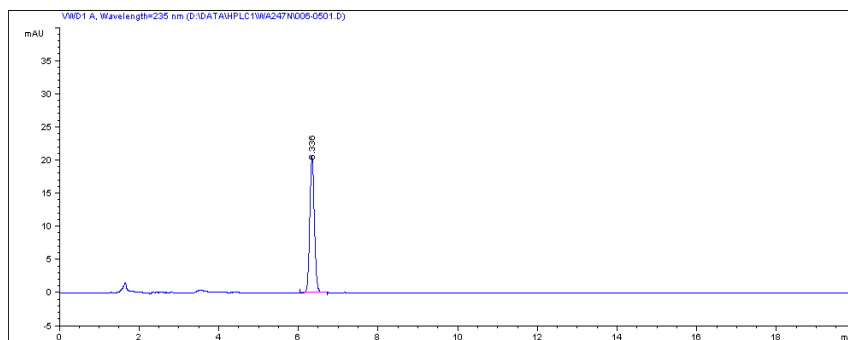
Reference solution: Dilute an accurately measured quantity of test solution with mobile phase to produce the reference solution of 2 µg/mL.

## Chromatographic conditions

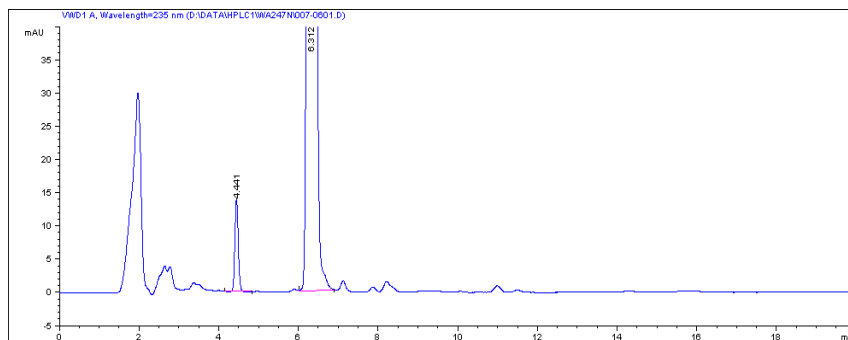
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: acetonitrile: water = 35:38:27
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 235 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA247N\006-0501



The chromatogram of the test solution--- HPLC1\WA247N\007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nimodipine	6.31	14394.3	15399	10.4	1.07
Impurity	4.44	81.5	12851	/	1.05

# Nitrendipine Tablets – 尼群地平片

Nitrendipine – Method number WR020

## Assay

Test solution: Protect from light throughout the procedure. Accurately weigh some tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in methanol to produce a solution containing 1 mg of nitrendipine per mL, filter and use the filtrate as the test solution.

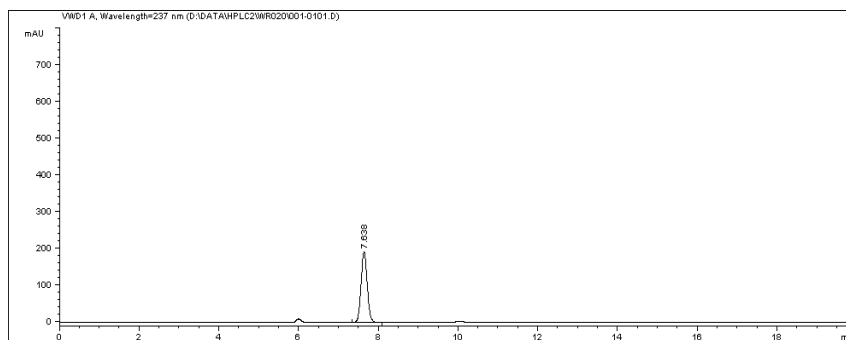
Reference solution: Dilute a quantity of the test solution with methanol to produce the reference solution of 50 µg/mL.

## Chromatographic conditions

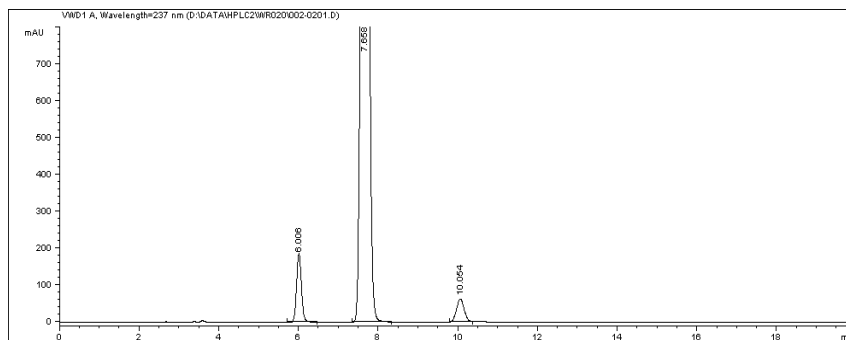
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 70:30
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 237 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR020001-0101.D



The chromatogram of the test solution--- HPLC2WR020002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Nitrendipine	7.66	40899.7	12290	6.6	1.05
Impurity1	6.01	1580.5	11927	/	1.08
Impurity2	10.05	861.3	12563	7.5	1.08

# Pantoprazole Sodium – 泮托拉唑钠

Pantoprazole sodium (100575-200301) – Method number WA275

## Assay

Test solution: Protect from light throughout the procedure. Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution containing 0.2 mg/mL.

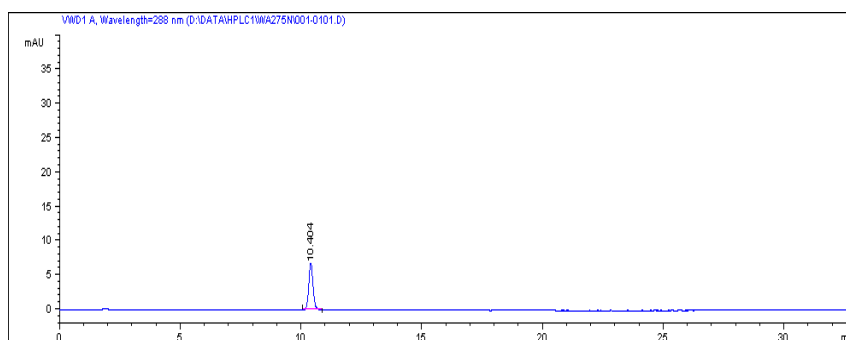
Reference solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the reference solution of 2 µg/mL.

## Chromatographic conditions

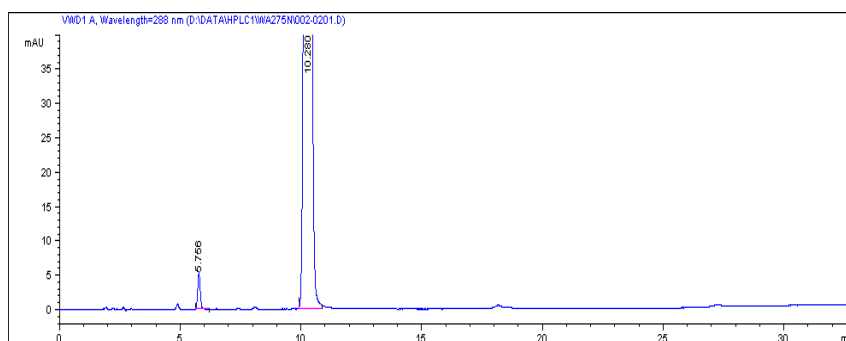
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile: phosphate BS (dissolve 1.12 g of disodium hydrogen phosphate and 0.18 g of sodium dihydrogen phosphate in water, dilute to 1000 mL, mix well, and adjust pH to 7.6) = 30:70
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 288 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA275N001-0101



The chromatogram of the test solution--- HPLC2WA275N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Pantoprazole Sodium	10.28	8940.8	16340	17.3	0.97
Impurity	5.76	38.6	13159	/	1.16

# Prednisone – 泼尼松

Prednisone (0199-9401) – Method number WR065

## Assay

Test solution: Dissolve a quantity in mobile phase in an amber volumetric flask, dilute to volume to produce the test solution containing 1.25 mg/mL.

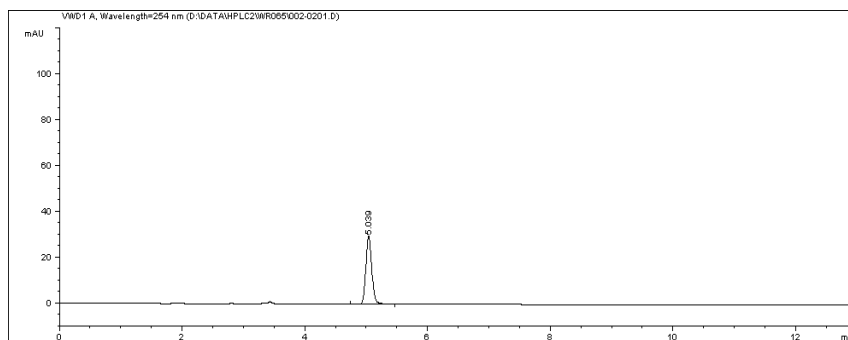
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

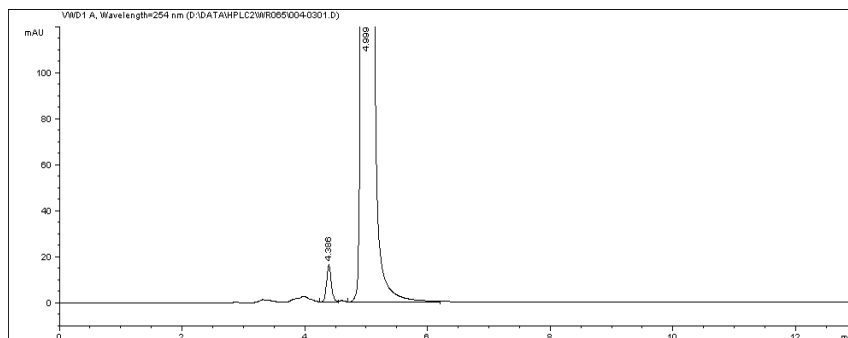
- Column: Agilent ZORBAX RX-Sil 4.6×250 mm, 5 µm (880975-901)
- Mobile phase: methanol:chloroform = 5:95
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR065002-0201



The chromatogram of the test solution---HPLC2WR065004-0301

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Prednisone	5.00	23120.4	12142	3.8	1.11
Impurity	4.39	93.5	16033	/	1.18

# Probucol – 普罗布考

Probucol (100560-200301) – Method number WA202

## Assay

Test solution: Dissolve a quantity of the substance in the mobile phase and dilute to produce the test solution of 1 mg/mL.

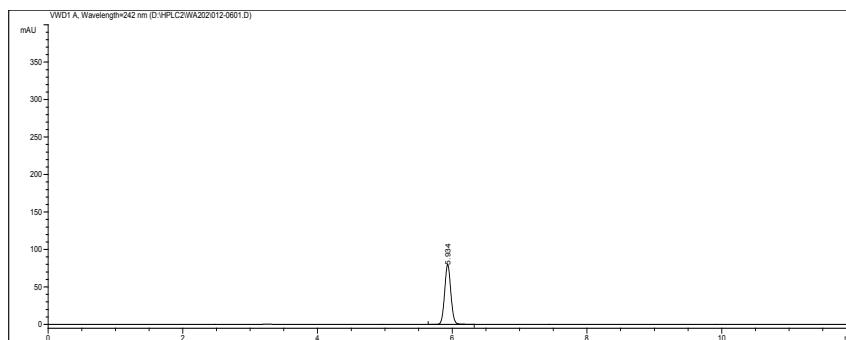
Reference solution: Dilute an accurately measured quantity of the test solution to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

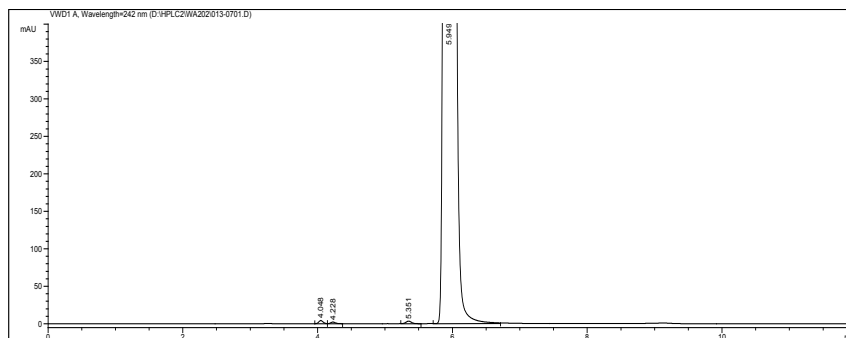
- Column: ZORBAX RX-Sil 4.6×250 mm, 5 µm (880975-901)
- Mobile phase: methanol : n-hexane = 1:1600
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 242 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA202\012-0601



The chromatogram of the test solution---HPLC2\WA202\013-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Probucol	5.95	35995.2	10616	3.1	1.14
Impurity1	4.05	19.4	18984	/	1.08
Impurity2	4.23	11.2	19107	1.5	1.25
Impurity3	5.35	19.6	20789	8.3	1.02



# Probuco<sup>®</sup> Tablets – 普罗布考片

Probuco<sup>®</sup>(100560-200301) – Method number WA203

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 25 mg of probuconol, in a 50 mL volumetric flask, add a quantity of the mobile phase and treat ultrasonically for 10 minutes to dissolve the probuconol. Allow to cool to room temperature, dilute to volume with mobile phase, mix well, filter and use the filtrate as the test solution.

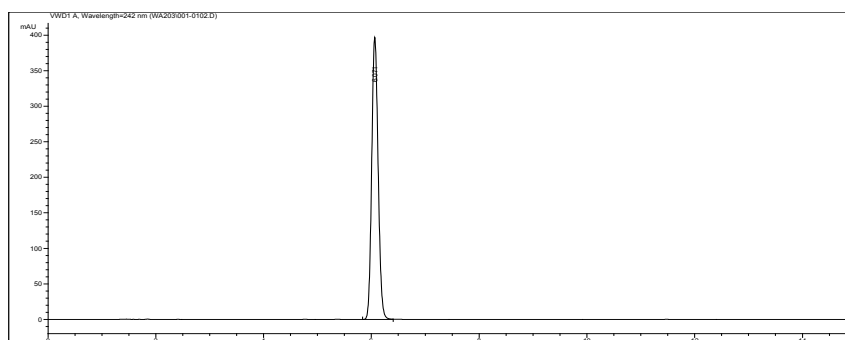
Reference solution: Repeat the procedure using probuconol CRS to produce the reference solution.

## Chromatographic conditions

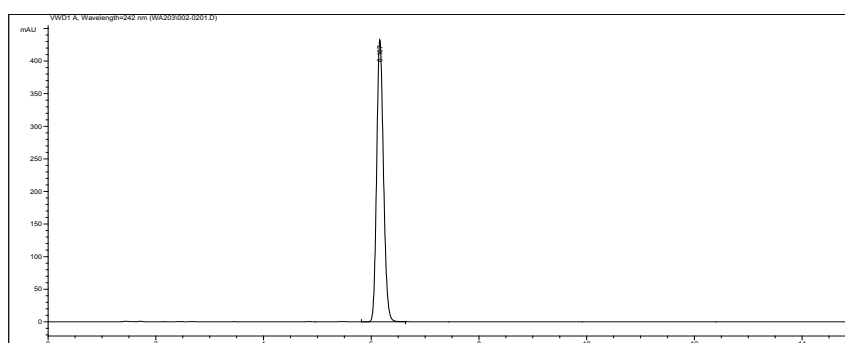
- Column: Agilent ZORBAX XDB-C8 4.6×150mm, 5 µm (993967-906)
- Mobile phase: water:acetonitrile = 5:95
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 242 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA203\001-0102



The chromatogram of the test solution--- HPLC1\WA203\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Probuconol	6.17	3790.7	10640	/	1.09

# Alprostadil – 前列地尔

Alprostadil (ARCOS) – Method number WA112

## Assay

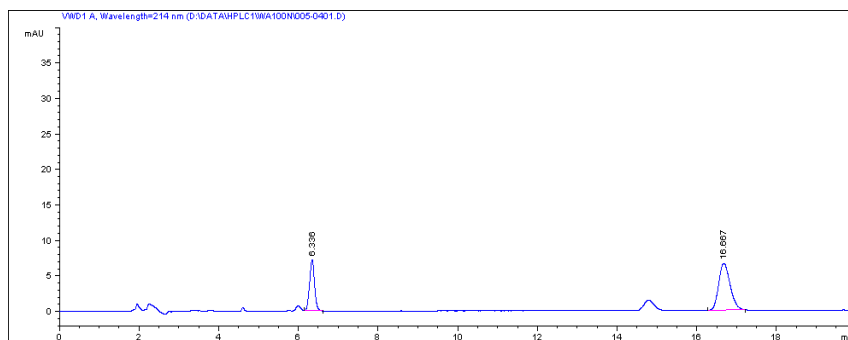
Test solution: Dissolve a quantity of the substance in mobile phase to produce the test solution of 0.05 mg/mL. To 2.0 mL of alprostadil CRS solution, add one drop of 0.1 mol/L sodium hydroxide solution, mix well, allow to stand for 1 hour and use for the system suitability test. The relative retention time of the peak of prostaglandin A1 is about 2.2-2.7.

## Chromatographic conditions

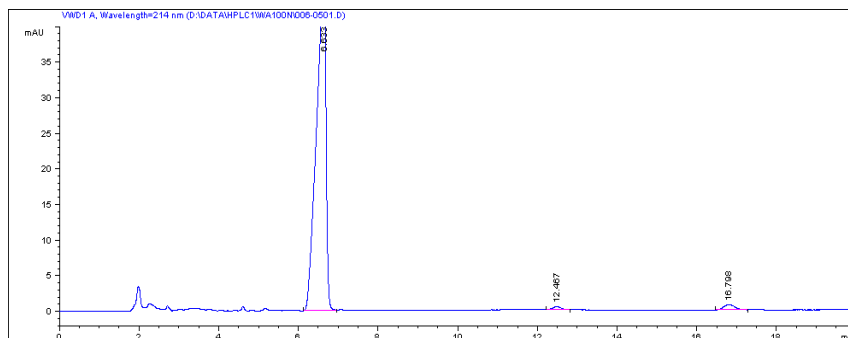
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile-0.02 mol/L potassium dihydrogen phosphate solution (pH 4.9) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 214 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the system suitability---HPLC1\WA100N002-0201



The chromatogram of the test solution--- HPLC1\WA100N004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Alprostadil	6.63	797.8	4488	/	0.68
Impurity	12.47	5.9	19769	15.7	1.20
Prostaglandin A1	16.80	14.8	17543	9.8	1.15

# Phenoxymethylpenicillin Potassium – 青霉素V钾

Benzylpenicillin K (0437-9501)

Phenoxymethylpenicillin potassium (0437-9501) – Method number WR071

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in phosphate BS (to 125 mL of 0.2 mol/L potassium dihydrogen phosphate solution, add 250 mL water, mix well, adjust pH to 6.5 with sodium hydroxide, dilute with water to 500 mL) and dilute to produce the test solution of 2.5 mg of phenoxymethylpenicillin potassium per mL.

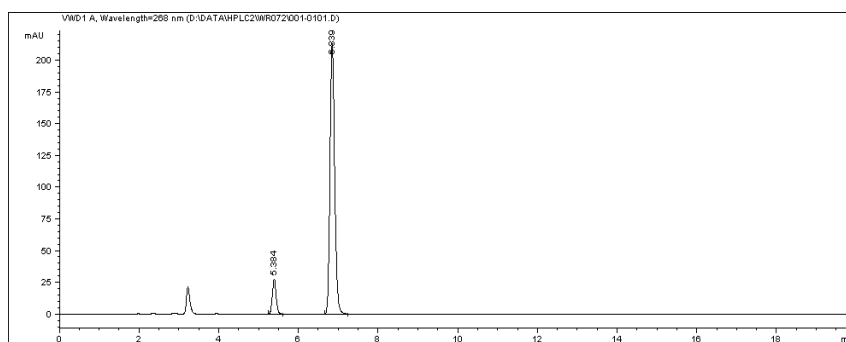
Reference solution: Transfer 1 mL of the test solution to a 100 mL volumetric flask, add phosphate BS (prepared as described above) to volume, mix well and use as the reference solution. Dissolve 10 mg each of benzylpenicillin K CRS and phenoxymethylpenicillin potassium CRS in phosphate solution in a 10 mL volumetric flask, dilute to volume, mix well and use for the system suitability test.

## Chromatographic conditions

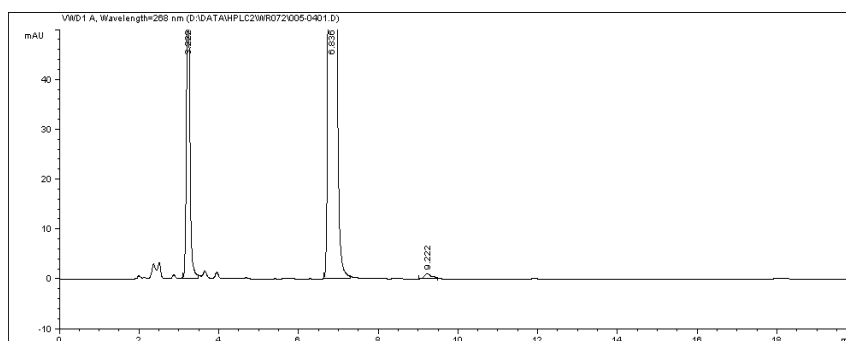
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water-acetonitrile-acetic acid = 60:40:1
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 268 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC2\WR072\001-0102.D



The chromatogram of the test solution --- HPLC2\WR072\005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Benzylpenicillin K	5.38	183.9	15835	/	1.07
phenoxymethylpenicillin K	6.84	1742.9	17141	7.6	1.13

# Phenoxymethylpenicillin Potassium Tablets – 青霉素V钾片

Phenoxymethylpenicillin Potassium (0437-9501) – Method number WR072

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 mg of phenoxymethylpenicillin, in a 50 mL volumetric flask, add phosphate solution (to 125 mL of 0.2 mol/L potassium dihydrogen phosphate solution, add 250 ml water, mix well, adjust pH to 6.5 with sodium hydroxide, dilute with water to 500 mL) to volume and mix well, filter and use the filtrate as the test solution.

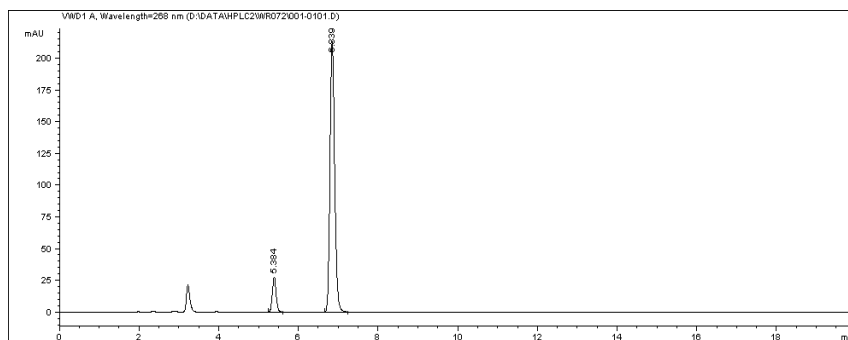
Reference solution: Produce a reference solution using phenoxymethylpenicillin potassium CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

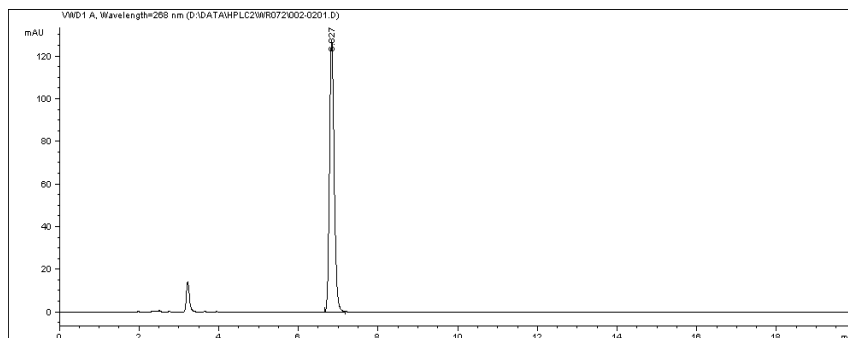
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: water-acetonitrile-acetic acid = 60:40:1
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 268 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC2\WR072\001-0101.D



The chromatogram of the test solution --- HPLC2\WR072\002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Phenoxymethylpenicillin K	6.83	1048.7	15060	/	1.12

# Phenoxymethylpenicillin Potassium Tablets – 青霉素V钾片

Phenoxymethylpenicillin Potassium (0437-9501) – Method number WR072

## Assay

**Test solution:** Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of powder in phosphate solution (to 125 mL of 0.2 mol/L potassium dihydrogen phosphate solution, add 250 mL water, mix well, adjust pH to 6.5 with sodium hydroxide, dilute with water to 500 mL) to produce a solution of 2.5 mg phenoxymethylpenicillin potassium per mL, filter and use the filtrate as the test solution.

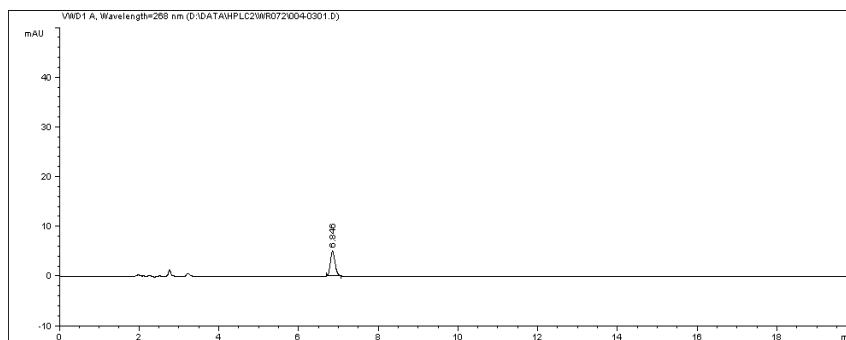
**Reference solution:** Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with phosphate solution (prepared as described above) to volume, mix well and use as the reference solution.

## Chromatographic conditions

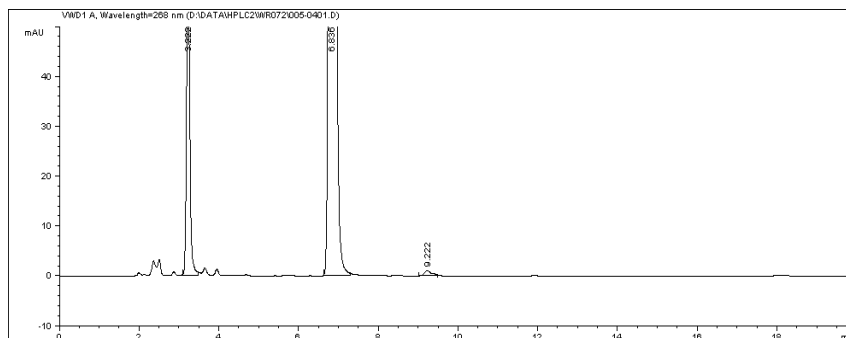
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water-acetonitrile-acetic acid = 60:40:1
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 268 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR072001-0101.D



The chromatogram of the test solution--- HPLC2WR072002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
phenoxymethylpenicillin K	6.84	4240.7	17587	20.6	1.10
Impurity1	3.22	356.0	8065	/	1.19
Impurity2	9.22	13.9	15870	9.5	/

# Benzylpenicillin Potassium – 青霉素钾

Benzylpenicillin Potassium (0437-9501) – Method number WR074

## Assay

Test solution: Dissolve an accurately weighed quantity in water to produce a solution of 0.5 mg/mL, mix well and use as the test solution.

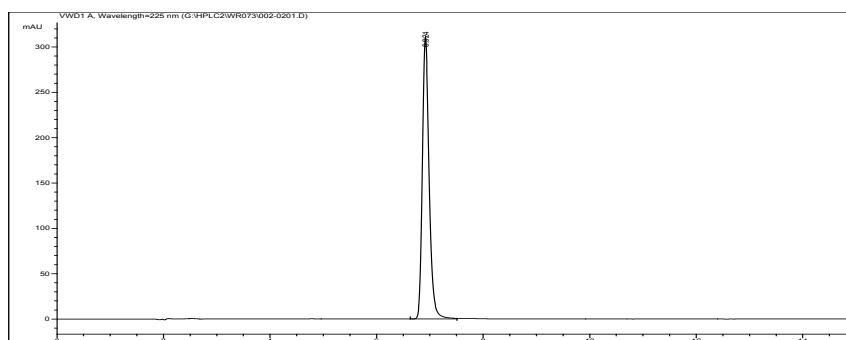
Reference solution: Dissolve a quantity of benzylpenicillin potassium CRS in water to produce the reference solution of 0.5 mg/mL.

## Chromatographic conditions

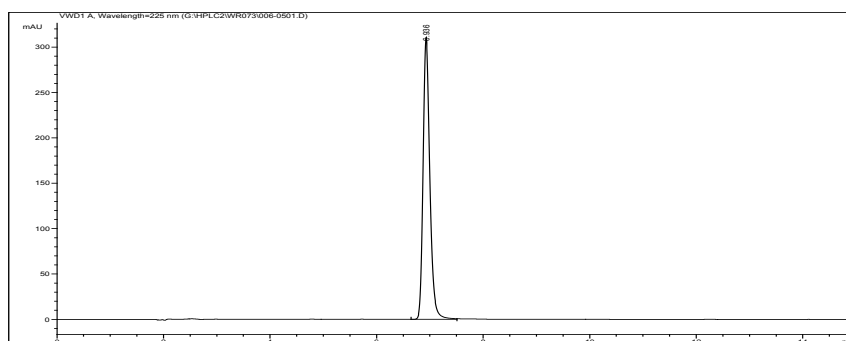
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5µm (880975-902)
- Mobile phase: 0.1 mol/L potassium dihydrogen phosphate solution (adjust pH to 2.5 with phosphoric acid)-acetonitrile (65: 35)
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 25 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR073002-0201.D



The chromatogram of the test solution--- HPLC2WR073006-0501.D D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Benzylpenicillin	6.94	2754.0	15523	/	1.17

# Benzylpenicillin Sodium – 青霉素钠

Benzylpenicillin Sodium (0437-9501) – Method number WR073

## Assay

Test solution: Dissolve an accurately weighed quantity in water to produce a solution of 0.5 mg/mL, mix well and use as the test solution.

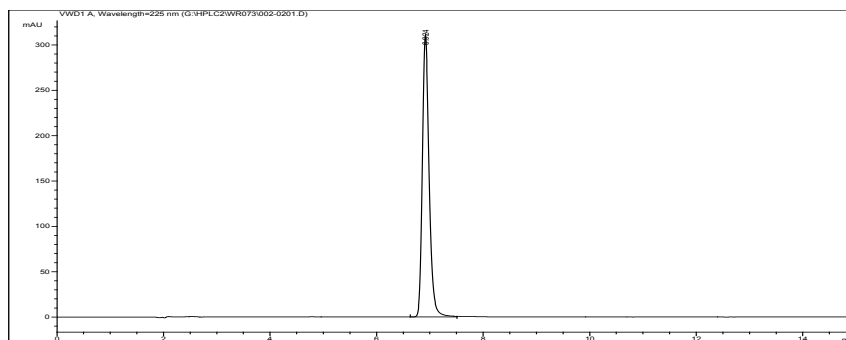
Reference solution: Dissolve a quantity of benzylpenicillin sodium CRS in water to produce the reference solution of 0.5 mg/mL.

## Chromatographic conditions

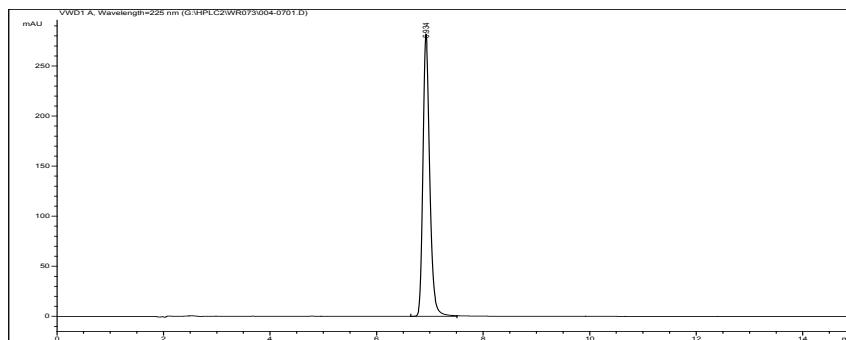
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water-acetonitrile-acetic acid =60:40:1
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR073002-0201.D



The chromatogram of the test solution--- HPLC2WR073004-0701.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Benzylpenicillin Sodium	6.93	2505	15137	/	1.17

# Hydrocortisone – 氢化可的松

Hydrocortisone (100152-200206) – Method number WR078

## Assay

**Test solution:** Accurately weigh about 12.5 mg of the substance in 25 mL volumetric flask, dissolve in tetrahydrofuran, dilute with water to volume, mix well and use as the test solution.

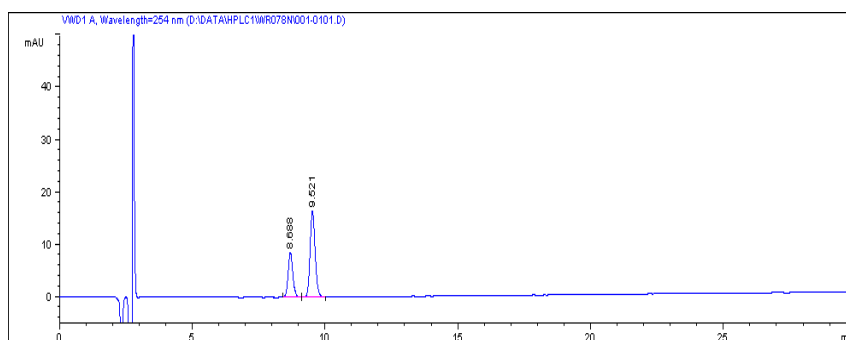
**Reference solution:** Accurately weigh about 12.5 mg of prednisolone CRS in a 50 mL volumetric flask, add 10 mL of tetrahydrofuran, dilute with water to volume, mix well and use as the reference solution. Accurately measure 1 mL each of test solution and reference solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use for the system suitability test.

## Chromatographic conditions

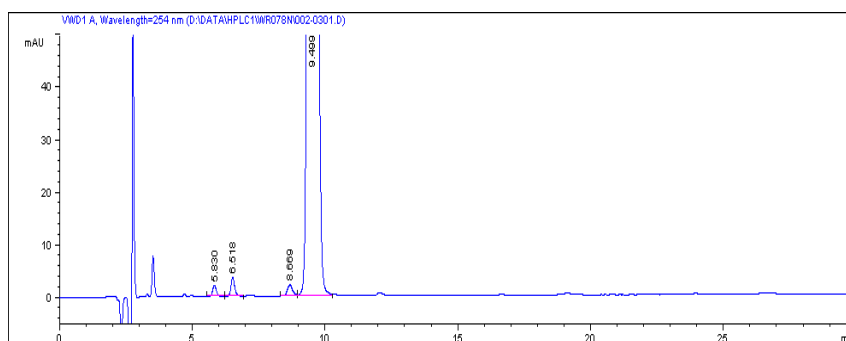
- Column: Agilent ZORBAX-XDB C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: tetrahydrofuran: water = 25:75
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC1\WR078N001-0101



The chromatogram of the test solution --- HPLC1\WR078N002-0301

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Hydrocortisone	9.52	218.7	12380	2.5	1.10
Prednisolone	8.69	104.8	12081	/	1.11



# Triamcinolone Acetonide and Econazole Nitrate Cream

Triamcinolone acetonide (100055-200302)

曲安奈德益康唑乳膏

## Assay

Internal standard solution: dissolve a quantity of ethyl p-hydroxybenzoate in methanol to produce a solution of 4.4 mg/mL, mix well.

Test solution: Accurately weigh about 1.25 g in a 25 mL volumetric flask, add 2 mL of tetrahydrofuran, shake for 1 minute, accurately add 5 mL of internal standard solution, dilute with methanol to volume, mix well, filter and use the filtrate as the test solution.

Reference solution: Accurately weigh about 15.6 mg triamcinolone acetonide CRS and 31.2 mg benzoic acid CRS in a 25 mL volumetric flask, dilute with methanol to volume and mix well. Accurately weigh about 12.5 mg of econazole nitrate CRS, accurately add 2 mL of the solution prepared above, 5 mL of internal standard solution and 2 mL of tetrahydrofuran, dilute with methanol to 25 mL, mix well and use as the reference solution.

### • Mobile phase:

A: hexane sulfonate sodium solution (dissolve 0.94 g of sodium hexane sulfonate in 1000 mL of a mixture of acetonitrile-isopropanol-water-85 % phosphoric acid = 140:140:720:1)

B: hexane sulfonate sodium (dissolve 0.94 g of sodium hexanesulfonate in 1000 mL of a mixture of methanol-water-85 % phosphoric acid = 900:100:1)

Gradient: 0 min, 0 %B;

10 min, 50 %A; 15 min, 100 %B;

20 min, 100 %B; 21 min, 0 %B;

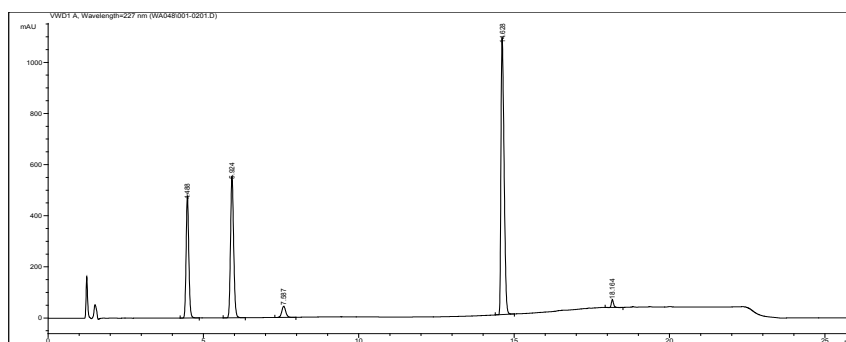
26 min, 0 %B

## Chromatographic conditions

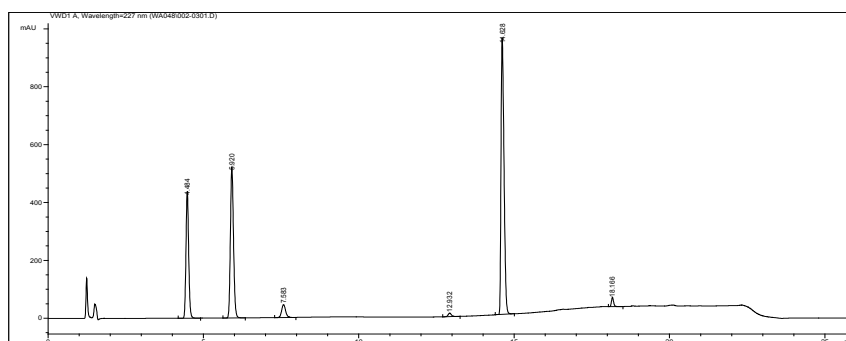
- Column: ZORBAX XDB-C8 4.6×150 mm, 5 μm (993967-906)
- Mobile phase: see assay
- Flow rate : 1.0 mL/ min
- Injection volume: 5 μL
- Column temperature: 40 °C
- Detector wavelength: 227 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA048\001-0201



The chromatogram of the test solution ---HPLC1\WA048\002-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Triamcinolone Acetonide	4.48	2636.1	12653	/	1.09
Ethyl-4-hydroxybenzoate	5.92	3610.9	16527	8.34	1.09
Benzoic Acid	7.58	394.7	17250	8.00	1.10
Econazole Nitrate	14.63	6354.0	107207	8.93	1.22

# Ethinylestradiol Tablets – 炔雌醇片

Ethinylestradiol (10052-200308) – Method number WA106

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 µg of ethinylestradiol, in a stoppered flask, add 10 mL of mobile phase, treat ultrasonically for 30 minutes until the ethinylestradiol dissolves. Shake well, centrifuge and use the supernatant as the test solution.

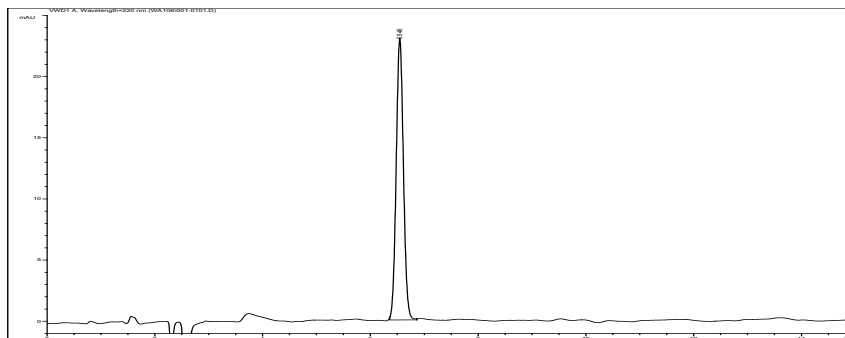
Reference solution: Dissolve an accurately weighed quantity of ethinylestradiol CRS in mobile phase and dilute with mobile phase to produce the reference solution of about 5 µg/mL.

## Chromatographic conditions

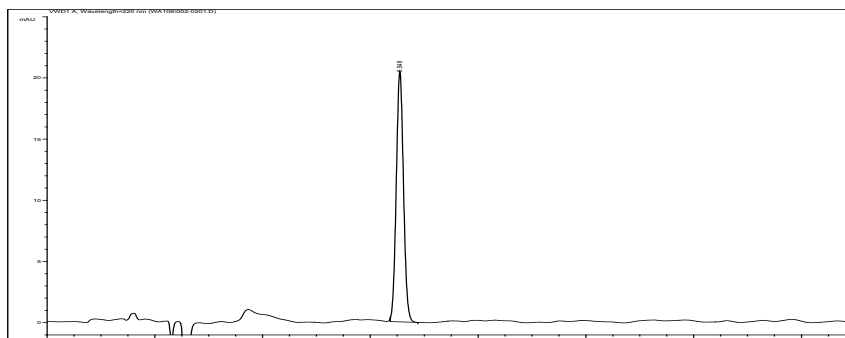
- Column : Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 70:30
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA106\001-0101



The chromatogram of the test solution --- HPLC2\WA106\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ethinylestradiol	6.55	192.2	11460	/	1.05

# Norethisterone – 炔诺酮

Norethisterone (100053-200204) – Method number WR169

## Assay

Test solution: Dissolve a quantity in methanol and dilute to produce the test solution of 2 mg/mL.

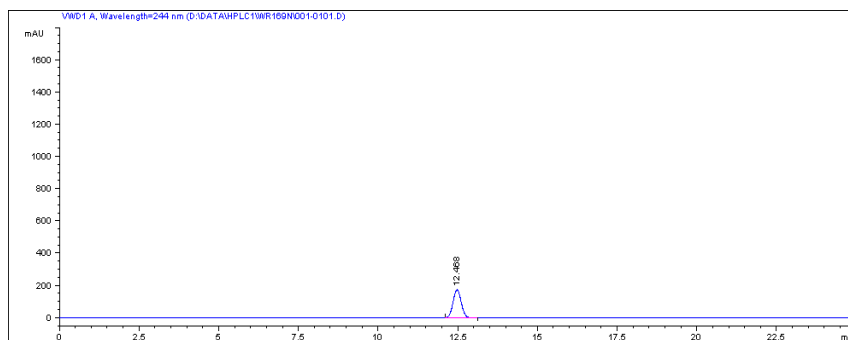
Reference solution: Accurately measure 3 mL of the test solution in a 100 mL volumetric flask, dilute to volume with methanol, mix well and use as the reference solution.

## Chromatographic conditions

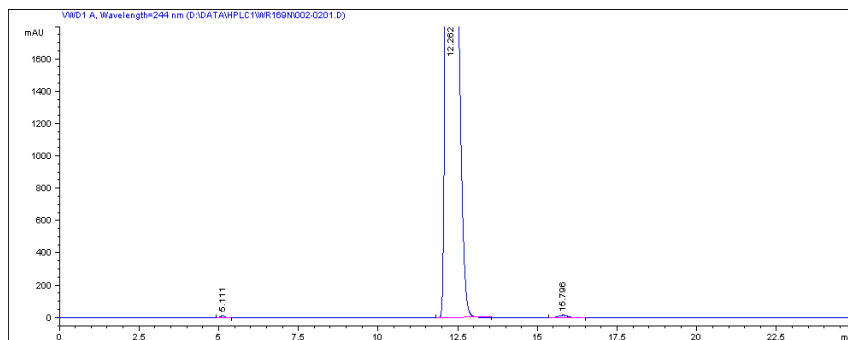
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 244 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR169\N001-0101



The chromatogram of the test solution ---HPLC1\WR169\N002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Norethisterone	12.26	99085.1	4271	14.2	1.45
Impurity1	5.11	135.3	6393	/	0.94
Impurity2	15.80	344.8	11641	5.3	1.02

# Norethisterone Tablets – 炔诺酮片

Norethisterone (100053-200204) – Method number WR170

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 1.25 mg of norethisterone, in a 10 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically until the norethisterone dissolves, dilute to volume with mobile phase, mix well, filter and use the filtrate as the test solution.

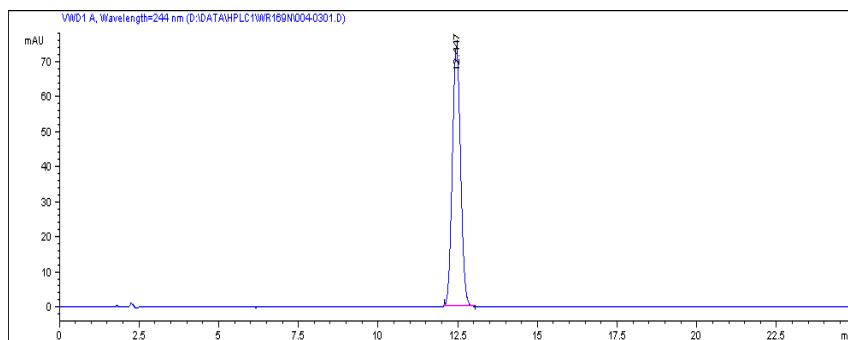
Reference solution: Dissolve an accurately weighed quantity of norethisterone CRS in mobile phase and dilute to produce the reference solution containing 25 µg/mL.

## Chromatographic conditions

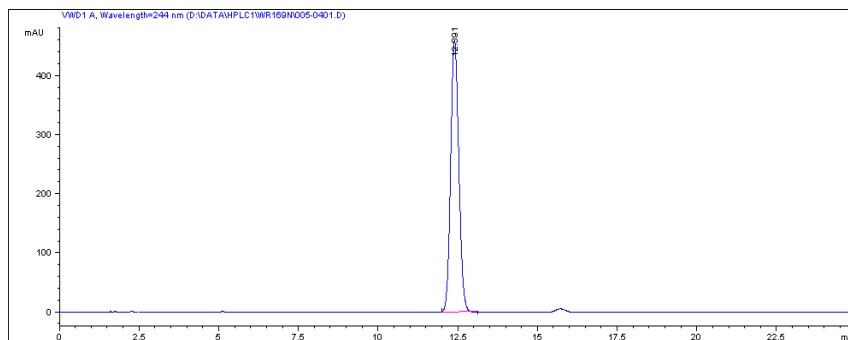
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 244 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WR169N004-0301



The chromatogram of the test solution---HPLC1\WR169N005-0401

Constituents (reference solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Norethisterone	12.45	1343.3	11021	/	1.05

# Adenosine Disodium Triphosphate – 三磷酸腺苷二钠

Adenosine disodium triphosphate (140674-200401) – Method number WA002

## Assay

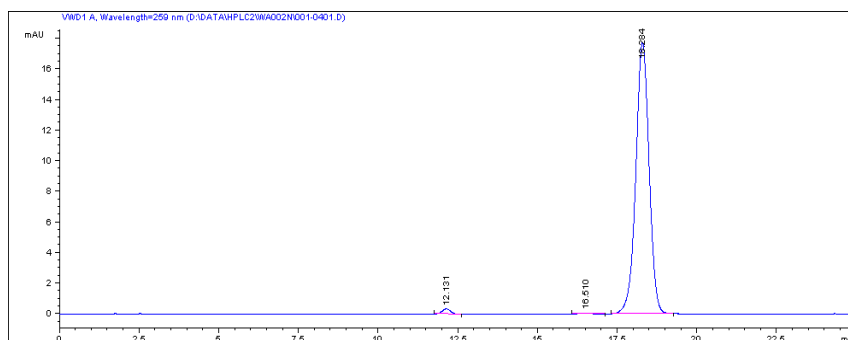
Test solution: Dissolve an accurately weighed quantity in mobile phase to produce the test solution of 40 µg/mL.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol : 0.2 mol/L phosphate BS (Dissolve 35.8 g of disodium hydrogen phosphate and 13.6 g of potassium dihydrogen phosphate in 900 ml of water, adjust to pH 7.0 with 1 mol/L sodium hydroxide solution, add 1.61 g of tetrabutylammonium bromide, add water to 1000 ml and mix well) = 8:92
- Column temperature: 35 °C
- Detector wavelength: 259 nm
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of test solution ---HPLC2WA002N001-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Adenosine Disodium monophosphate	12.13	6.5	10114	/	0.96
Adenosine Disodium diphosphate	16.51	2.0	10143	7.7	/
Adenosine Disodium triphosphate	18.28	516.5	9707	2.5	0.97

# Adenosine Disodium Triphosphate Injection

Adenosine disodium triphosphate – Method number WA232

三磷酸腺苷二钠注射液

## Assay

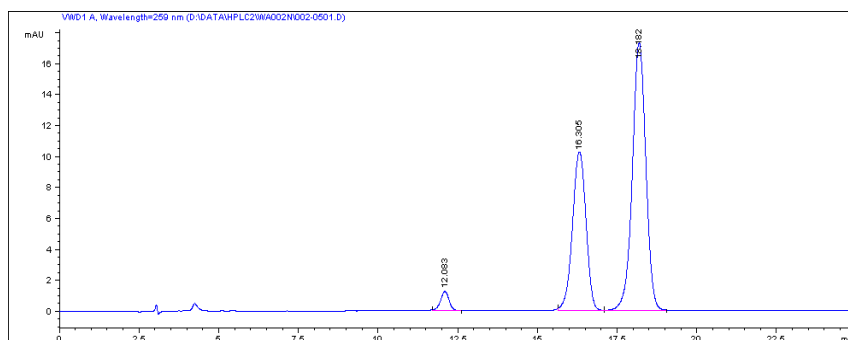
Test solution: Dissolve an accurately measured quantity of injection fluid in mobile phase to produce a solution of 40 µg/mL.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol: 0.2 mol/L phosphate BS (dissolve 35.8 g of disodium hydrogen phosphate and 13.6 g of potassium dihydrogen phosphate in 900 mL of water, adjust pH to 7.0 with 1 mol/L sodium hydroxide solution, add 1.61 g of tetrabutylammonium bromide, add water to 1000 mL and mix well) =8 :92
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 35 °C
- Detector wavelength: 259 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the test solution ---HPLC2WA002N002-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Adenosine Disodium monophosphate	12.08	23.3	9865	/	0.91
Adenosine Disodium diphosphate	16.31	302.9	7002	6.7	0.94
Adenosine Disodium triphosphate	18.18	511.8	9186	2.4	0.96

# Triazolam Tablets – 三唑仑片

Triazolam (1230-9701) – Method number WR002

## Assay

Test solution: Accurately weigh 50 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 6 mg of triazolam, in a 100 mL volumetric flask, accurately add 50 mL of 50 % methanol solution, warm gently and shake to dissolve the triazolam, allow to cool and dilute with 50 % methanol solution to volume, filter and use the filtrate as the test solution.

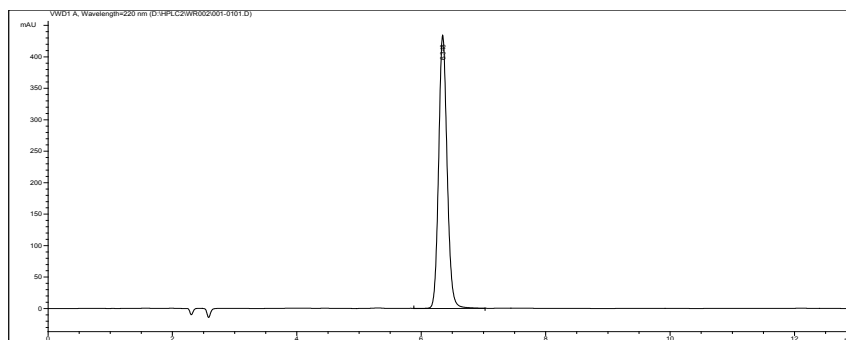
Reference solution: Dissolve an accurately weighed quantity of triazolam CRS dried to constant weight at 105 °C in 50 % methanol solution (treat ultrasonically to dissolve, if necessary) to produce the reference solution of 0.12 mg/mL.

## Chromatographic conditions

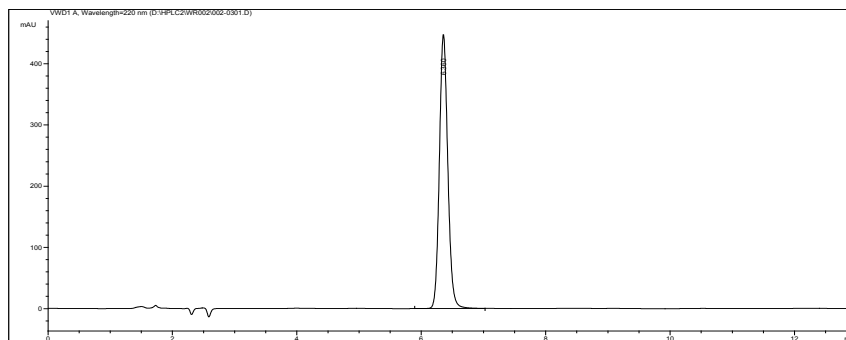
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water = 65:35
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA002001-0101



The chromatogram of the test solution --- HPLC2WA002002-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Triazolam	6.36	4209.9	9007	/	1.09

# Testosterone Undecanoate Soft Capsules – 十一酸睾酮软胶囊

Testosterone undecanoate (0242-9501) – Method number WA001

## Assay

Test solution: Accurately weigh a quantity of the contents of the capsules, add methanol to dissolve the testosterone undecanoate and dilute with methanol to produce the test solution of 50 µg/mL.

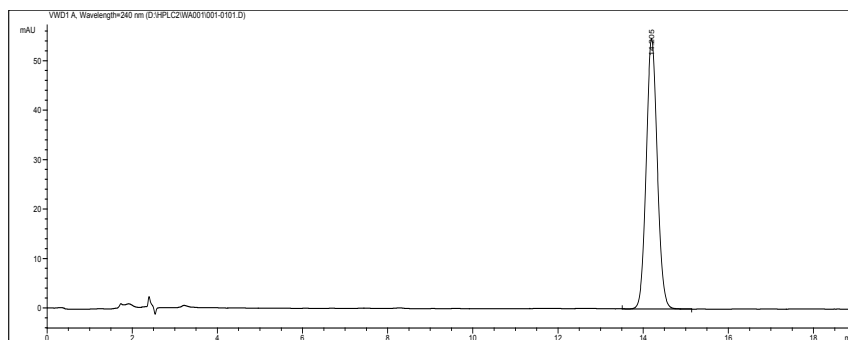
Reference solution: Prepare as described for the test solution.

## Chromatographic conditions

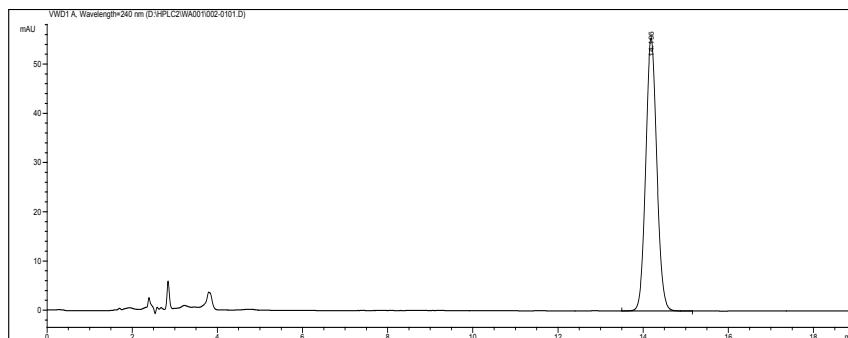
- Column: Agilent ZORBAX Eclipse XDB C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile : isopropanol : water = 43:43:14
- Column temperature: 30 °C
- Detector wavelength: 240 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of chemical reference substance ---HPLC2WA001V001-0101



The chromatogram of test solution---HPLC2WA001V002-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Testosterone	14.19	1000.2	14328	/	1.05



# Huperzine-A – 石杉碱甲

Huperzine-A (100243-200401) – Method number WA032

## Assay

Test solution: Dissolve a quantity of the substance in 0.01 mol/L hydrochloric acid solution to produce the test solution of 0.1 mg/mL.

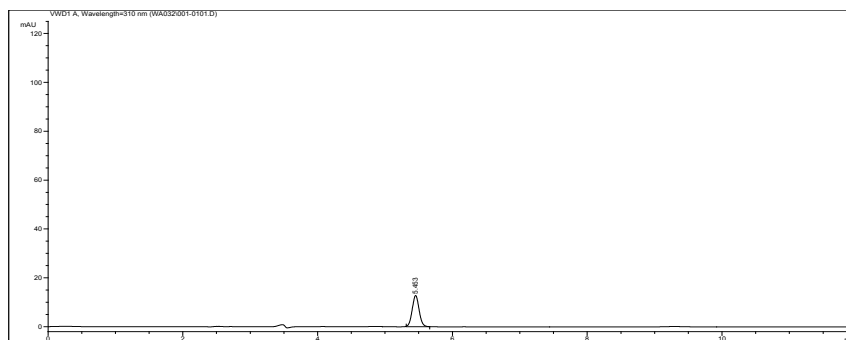
Reference solution: Dissolve a quantity of the substance in 0.01 mol/L hydrochloric acid solution to produce the reference solution of 0.2 µg/mL.

## Chromatographic conditions

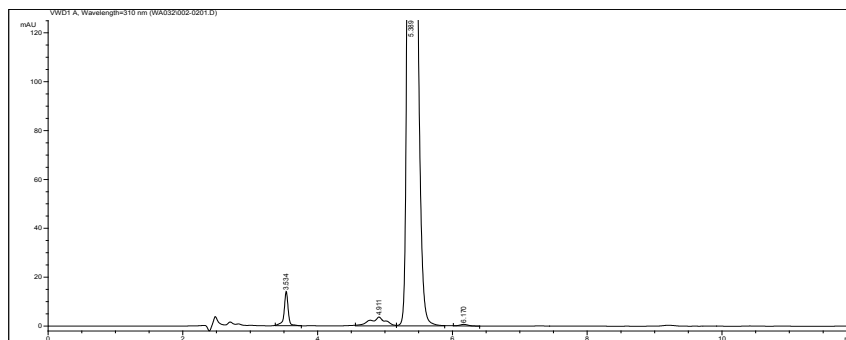
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile:phosphate buffer (dissolve potassium dihydrogen phosphate 2.72 g in 1000 mL of water, adjust to pH 2.5 with phosphoric acid) = 14:86
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA032001-0101



The chromatogram of the test solution--- HPLC2WA032002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Huperzine-A	5.39	3637.1	11227	1.33	1.35
Impurity1	3.53	58.7	21831	/	0.82
Impurity2	4.91	57.3	1460	4.51	0.87
Impurity3	6.17	5.80	12281	3.66	0.94

# Huperzine A Capsules – 石杉碱甲胶囊

## Huperzine A (100243-200401) – Method number WA035

### Assay

Test solution: Accurately weigh the contents of 20 capsules and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.1 mg of huperzine A, in a 10 mL volumetric flask, add a quantity of 0.01 mol/L hydrochloric acid solution, treat ultrasonically to dissolve the huperzine A, dilute with 0.01 mol/L hydrochloric acid solution to volume, shake thoroughly, filter and use the filtrate as the test solution.

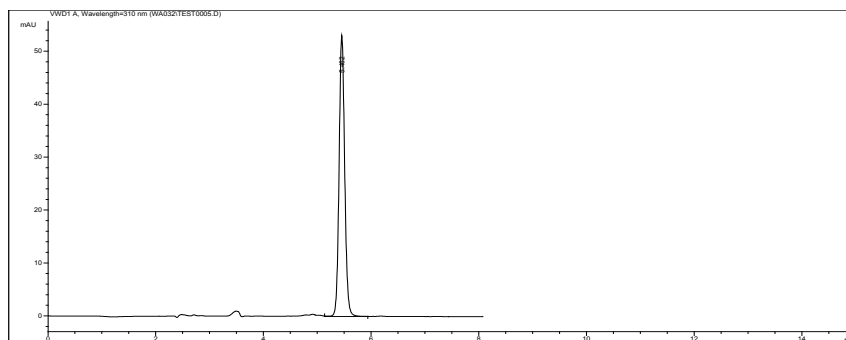
Reference solution: Repeat the procedure using huperzine A CRS to produce the reference solution.

### Chromatographic conditions

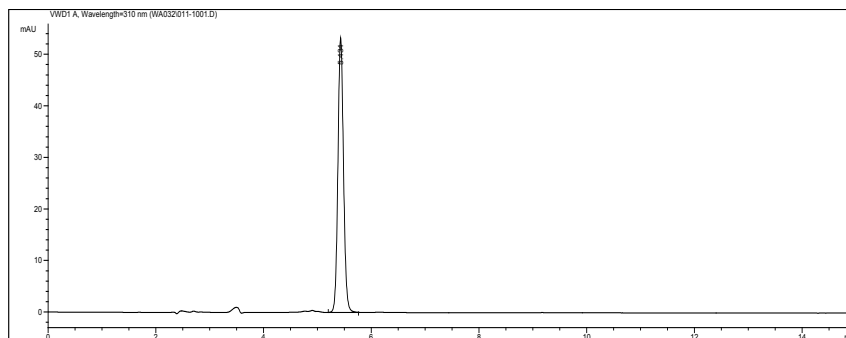
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile:phosphate buffer (dissolve potassium dihydrogen phosphate 2.72 g in 1000 mL of water, adjust to pH 2.5 with phosphoric acid) = 14:86
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA032\TEST0005



The chromatogram of the test solution --- HPLC1\WA032\014-1301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Huperzine-A	5.43	377.1	13101	/	1.06

# Huperzine A Tablets – 石杉碱甲片

Huperzine-A (100243-200401) – Method number WA033

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.1 mg of huperzine A, in a 10 mL volumetric flask, add a quantity of 0.01 mol/L hydrochloric acid solution and treat ultrasonically to dissolve the huperzine A, dilute with 0.01 mol/L hydrochloric acid solution to volume, shake thoroughly, filter and use the filtrate as the test solution.

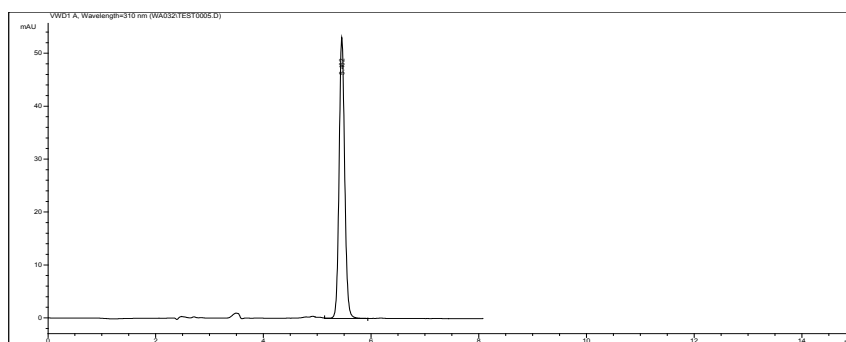
Reference solution: Repeat the procedure using huperzine A CRS to produce the reference solution.

## Chromatographic conditions

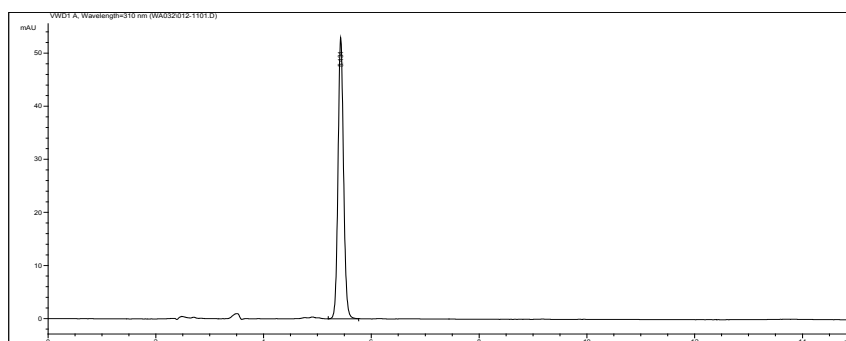
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile:phosphate buffer (dissolve potassium dihydrogen phosphate 2.72 g in 1000 mL of water, adjust to pH 2.5 with phosphoric acid) = 14:86
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA032\TEST0005



The chromatogram of the test solution--- HPLC1\WA032\012-1101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Huperzine-A	5.43	378.3	12055	/	1.07

# Huperzine A Tablets – 石杉碱甲片

## Huperzine A (100243-200401) – Method number WA033

### Assay

Test solution: Add 0.01 mol/L hydrochloric acid to a quantity of powdered tablets to produce a solution of about 0.1 mg of huperzine A per ml, filter and use the filtrate as the test solution.

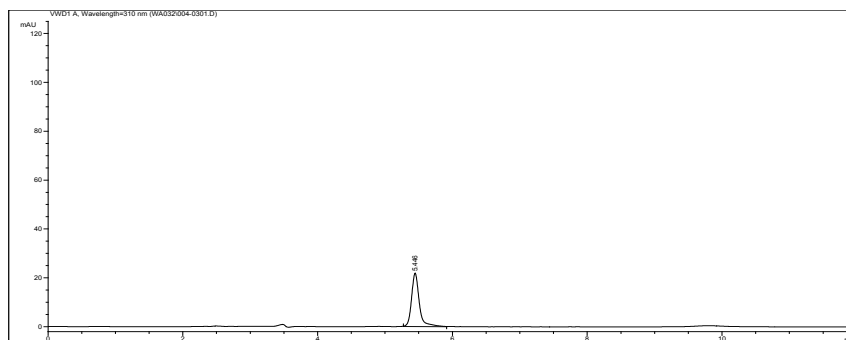
Reference solution: Accurately measure a quantity of the test solution, dilute with the same solvent to produce the reference solution of 0.4 µg/mL.

### Chromatographic conditions

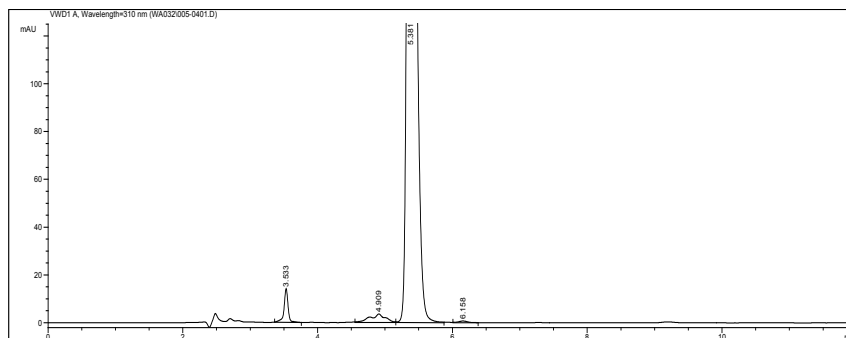
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile:phosphate buffer (dissolve potassium dihydrogen phosphate 2.72 g in 1000 mL of water, adjust to pH 2.5 with phosphoric acid)=14:86
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA032004-0301



The chromatogram of the test solution --- HPLC1WA032005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Huperzine-A	5.38	3641.2	11192	1.30	1.35
Impurity1	3.53	58.9	21815	/	0.81
Impurity2	4.91	57.7	1428	4.47	0.86
Impurity3	6.16	6.6	11377	3.57	1.09

# Huperzine A Injection – 石杉碱甲注射液

Huperzine A (100243-200401) – Method number WA034

## Assay

Test solution: Accurately measure a quantity of the injection fluid and add 0.01 mol/L hydrochloric acid solution to produce the test solution of 40 µg of huperzine A per mL.

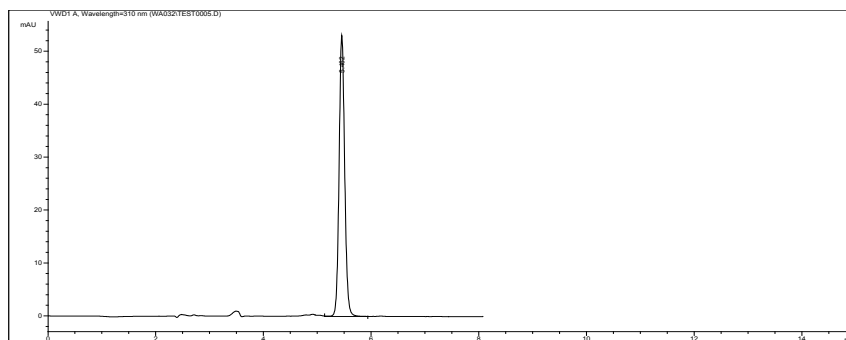
Reference solution: Repeat the procedure using huperzine A CRS to produce the reference solution.

## Chromatographic conditions

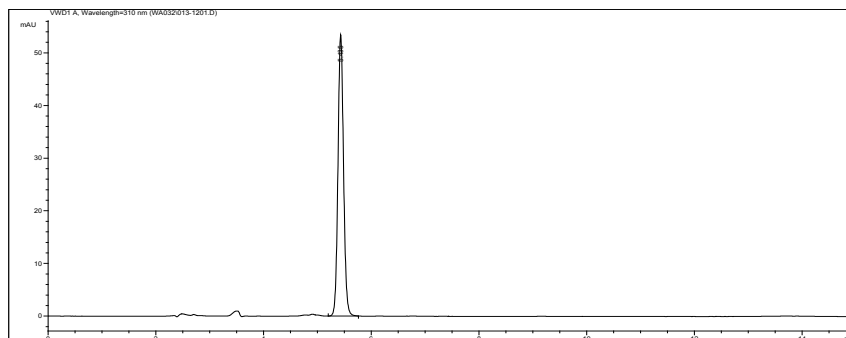
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile:phosphate buffer (dissolve potassium dihydrogen phosphate 2.72 g in 1000 mL of water, adjust to pH 2.5 with phosphoric acid)=14:86
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA032\TEST0005



The chromatogram of the test solution --- HPLC1\WA032\013-1201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Huperzine-A	5.44	381.7	12405	/	1.06

# Sparfloxacin – 司帕沙星

## Sparfloxacin –Method number WA007

### Assay

Test solution: Dissolve a quantity of the substance in methanol to produce an intermediate solution of 0.2 mg/mL. Measure a quantity of the intermediate solution and dilute with mobile phase to produce the test solution containing 0.05 mg/mL.

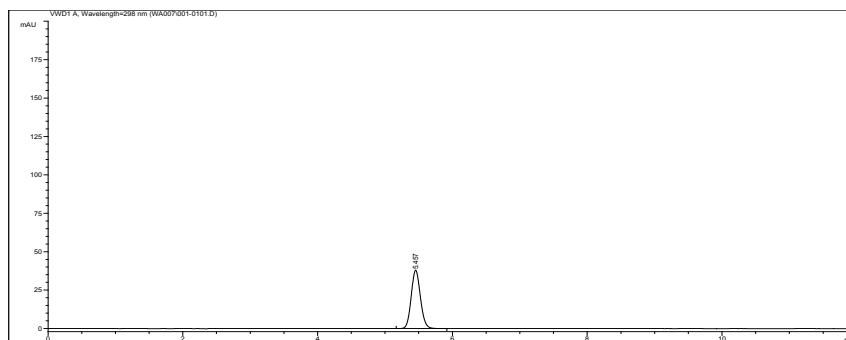
Reference solution: Measure a quantity of the intermediate solution and dilute with mobile phase to produce the reference solution of 3 µg/mL.

### Chromatographic conditions

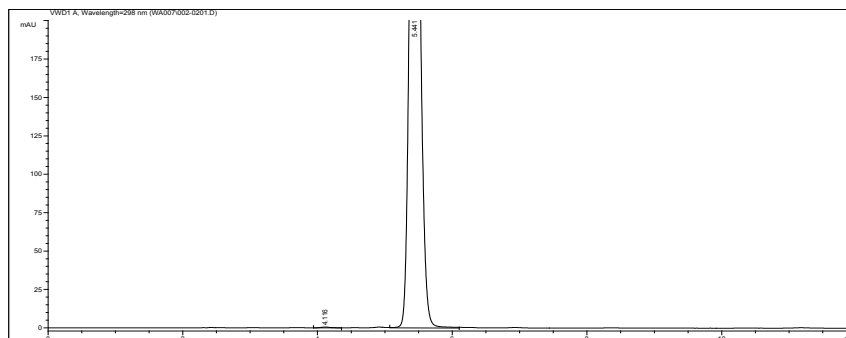
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: phosphate BS (dissolve 6.8 g of potassium dihydrogen phosphate and 3.0 ml of triethylamine in 1000 ml of water and mix well, adjust pH value to 2.5 with phosphoric acid):methanol = 45 : 55
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 298 nm

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA007001-0101



The chromatogram of the test solution --- HPLC2WA007002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity	4.12	4.8	5466	/	1.14
Sparfloxacin	5.45	4888.3	5920	5.53	1.08

# Sparfloxacin Capsules – 司帕沙星胶囊

Sparfloxacin – Method number WA009

## Assay

Test solution: Accurately weigh a quantity of the well-mix contents, equivalent to about 50 mg of sparfloxacin, in a 100 mL volumetric flask, dissolve in a quantity of methanol, dilute to volume, mix well and filter. Accurately measure 2 mL of the filtrate in a 25 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

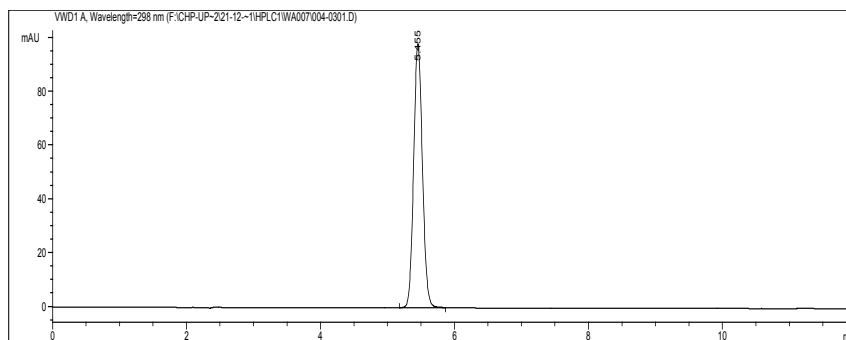
Reference solution: Repeat the procedure using sparfloxacin CRS to produce the reference solution.

## Chromatographic conditions

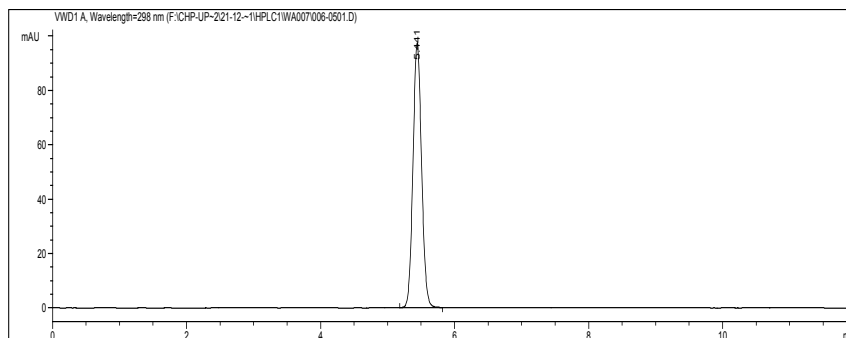
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: phosphate BS (dissolve 6.8 g of potassium dihydrogen phosphate and 3.0 ml of triethylamine in 1000 ml of water and mix well, adjust pH value to 2.5 with phosphoric acid):methanol = 45 : 55
- Column temperature: 30 °C
- Detector wavelength: 298 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA007004-0301



The chromatogram of the test solution --- HPLC1WA007006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Sparfloxacin	5.45	871.1	7106	/	1.04

# Sparfloxacin Tablets – 司帕沙星片

Sparfloxacin – Method number WA008

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 mg of sparfloxacin, in a 100 ml volumetric flask, dissolve in a quantity of methanol, dilute to volume, mix well and filter. Accurately measure 2 mL of the filtrate in a 25 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

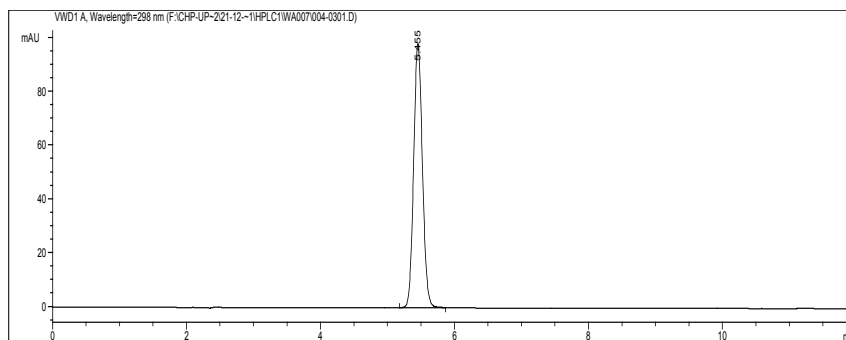
Reference solution: Repeat the procedure using sparfloxacin CRS to produce the reference solution.

## Chromatographic conditions

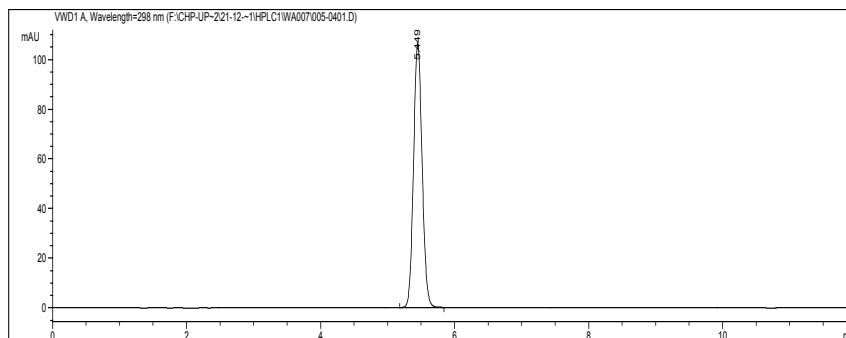
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: phosphate BS (dissolve 6.8 g of potassium dihydrogen phosphate and 3.0 ml of triethylamine in 1000 ml of water and mix well, adjust pH value to 2.5 with phosphoric acid):methanol = 45 : 55
- Column temperature: 30 °C
- Detector wavelength: 298 nm
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA007004-0301



The chromatogram of the test solution --- HPLC2WA007005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Sparfloxacin	5.46	955.7	7442	/	1.05



# Tinidazole – 替硝唑

Tinidazole (10336-0001) – Method number WA204

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution of 1 mg/mL.

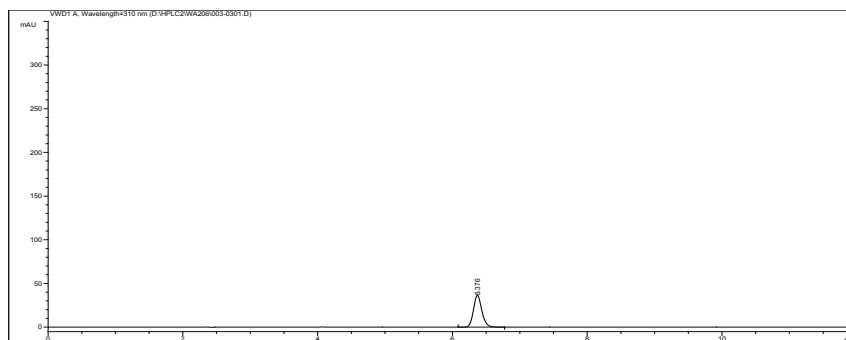
Reference solution: Dilute an accurately measured quantity of the test solution to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

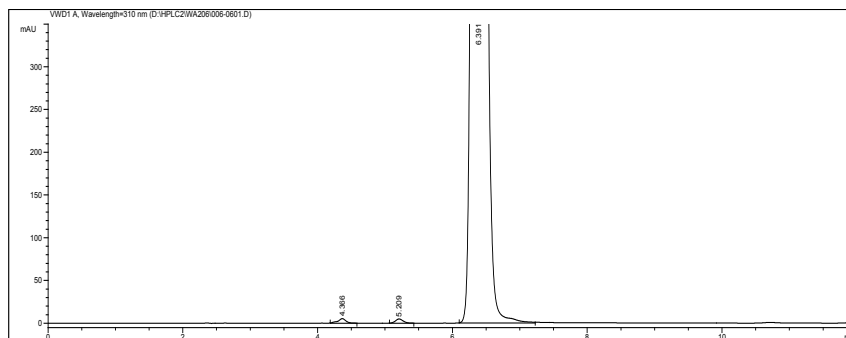
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 3.5 with phosphoric acid) –methanol (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA206003-0301



The chromatogram of the test solution--- HPLC2WA206006-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tinidazole	6.39	38965.9	8072	4.8	1.06
Impurity1	4.37	43.4	8857	/	0.90
Impurity2	5.21	38.9	10417	4.3	1.11

# Tinidazole Capsules – 替硝唑胶囊

## Tinidazole (10336-0001) – Method number WA208

### Assay

Test solution: Accurately weigh a quantity of the powdered and well-mixed contents, equivalent to about 30 mg of tinidazole in a 25 mL volumetric flask, add a quantity of mobile phase and shake to dissolve the tinidazole. Dilute to volume with mobile phase, mix well and filter. Accurately measure 5 mL of the filtrate, in a 50 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the test solution.

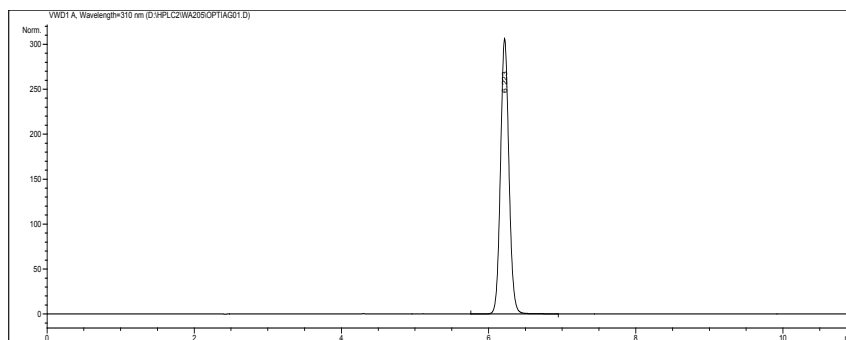
Reference solution: Repeat the procedure using tinidazole CRS to produce the reference solution.

### Chromatographic conditions

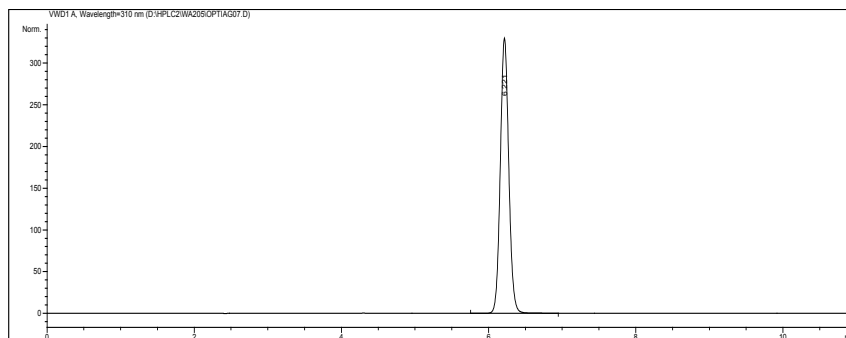
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 3.5 with phosphoric acid) - methanol (75:25)
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA205\OPTIAG01



The chromatogram of the test solution---HPLC2\WA205\OPTIAG07

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tinidazole	6.22	2628.2	13804	/	1.05

# Tinidazole Tablets – 替硝唑片

Tinidazole (10336-0001) – Method number WA205

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 30 mg of tinidazole, in a 25 mL volumetric flask, add a quantity of mobile phase, shake to dissolve the tinidazole, dilute to volume with the mobile phase, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute to volume with mobile phase and use as the test solution.

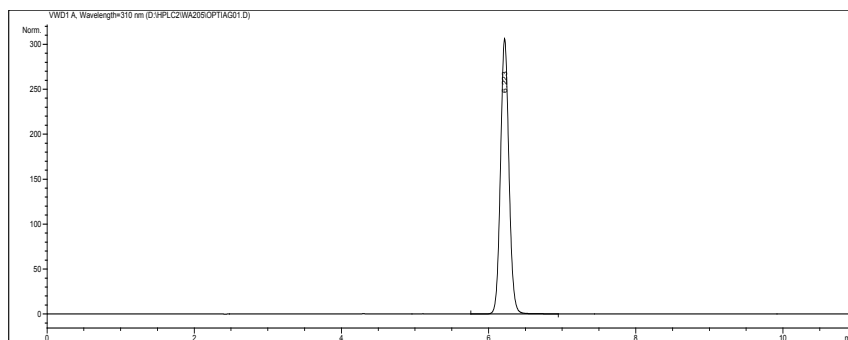
Reference solution: Dilute a quantity of tinidazole CRS with mobile phase to produce the reference solution containing 0.12 mg/mL.

## Chromatographic conditions

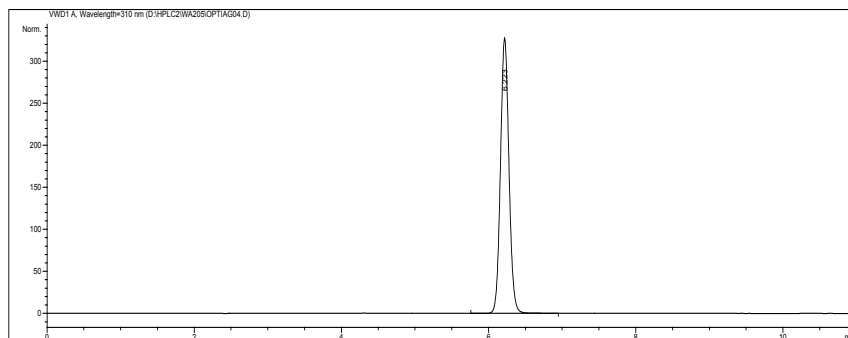
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 3.5 with phosphoric acid) –methanol (75:25)
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA205\OPTIAG01



The chromatogram of the test solution---HPLC2\WA205\OPTIAG04

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tinidazole	6.22	2633.1	13815	/	1.05

# Tinidazole and Glucose Injection – 替硝唑葡萄糖注射液

Tinidazole (10336-0001) – Method number WA256

## Assay

Test solution: Dilute an accurately measured quantity with mobile phase to produce the test solution of 100 µg/mL.

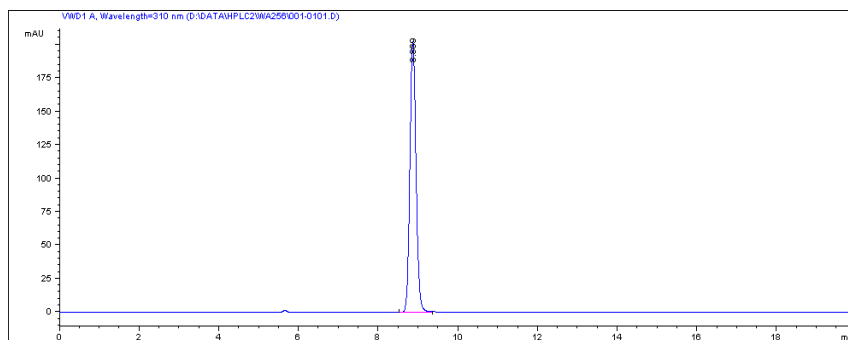
Reference solution: Repeat the operation using tinidazole CRS to produce the reference solution.

## Chromatographic conditions

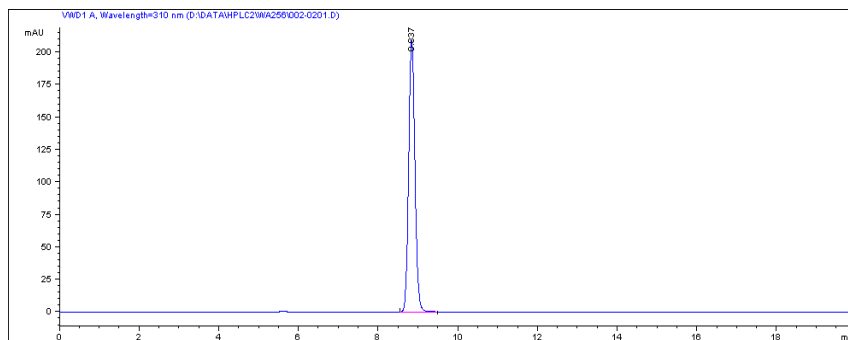
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol : 0.05M sodium dihydrogen phosphate (pH 3.5)=25:75
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA256\001-0101



The chromatogram of the test solution --- HPLC2\WA256\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Tinidazole	8.84	2306.1	15431	/	1.07

# Tinidazole and Glucose Injection – 替硝唑葡萄糖注射液

Tinidazole (10336-0001) – Method number WA256

## Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce the test solution of 800 µg/mL.

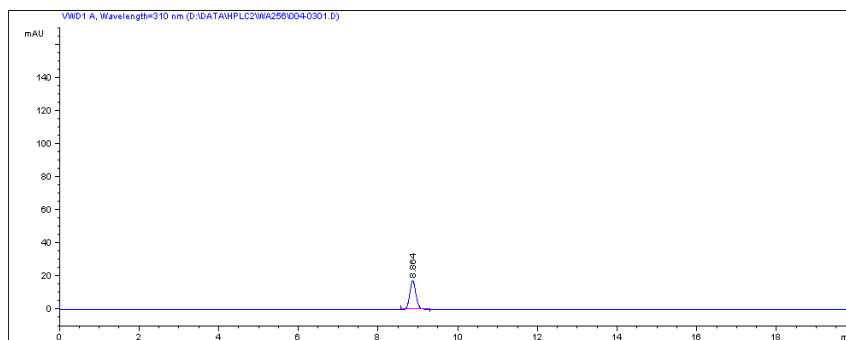
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce reference the solution of 8 µg/mL.

## Chromatographic conditions

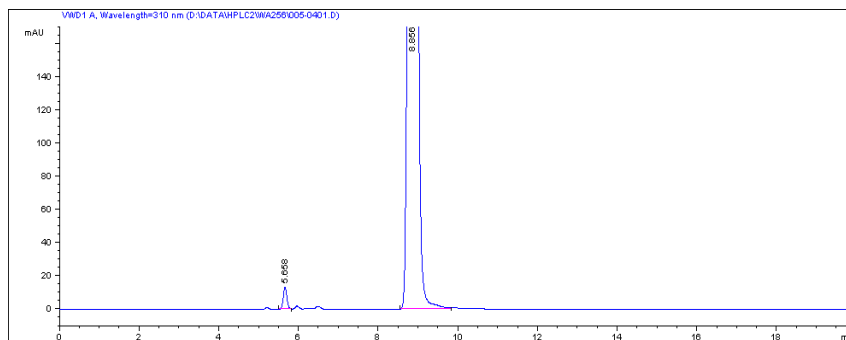
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol: 0.05 M sodium dihydrogen phosphate (pH 3.5)=25:75
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA256\004-0301



The chromatogram of the test solution --- HPLC2\WA256\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Tinidazole	8.86	17723.8	16437	14.5	1.06
Impurity1	5.66	85.2	18821	/	1.08

# Tinidazole Suppositories – 替硝唑栓

Tinidazole (10336-0001) – Method number WA207

## Assay

Test solution: Accurately weigh 10 suppositories and cut into pieces. Accurately weigh a quantity, equivalent to about 30 mg of tinidazole, in a 25 mL volumetric flask. Add a quantity of mobile phase, heat on a water bath and shake to dissolve the tinidazole, allow to cool to room temperature, dilute with mobile phase to volume, mix well. Cool in ice bath for 1 hour, filter immediately and allow the filtrate to reach room temperature. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

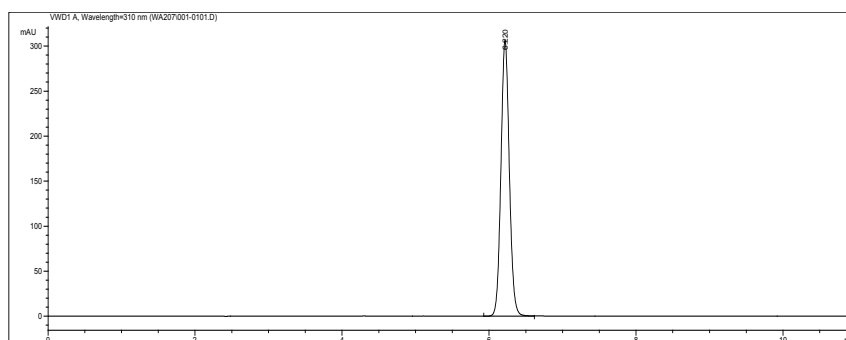
Reference solution: Repeat the procedure using tinidazole CRS to produce the reference solution.

## Chromatographic conditions

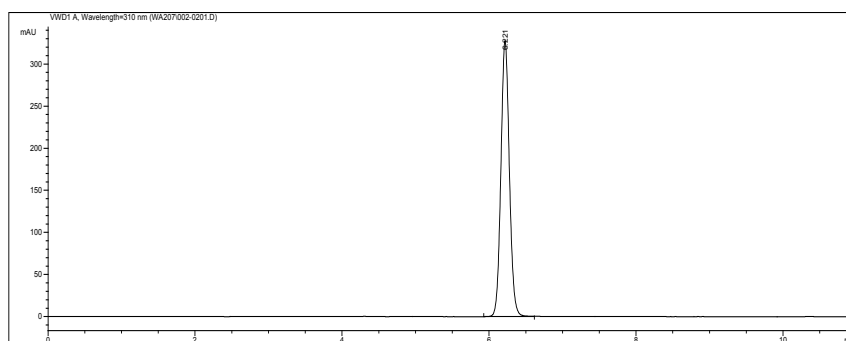
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 3.5 with phosphoric acid) –methanol (75:25)
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA207\001-0101



The chromatogram of the test solution--- HPLC1\WA207\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tinidazole	6.22	2623.1	13815	/	1.05

# Tinidazole Injection – 替硝唑注射液

Tinidazole (10336-0001) – Method number WA206

## Assay

Test solution: Dilute an accurately measured quantity of the injection fluid with mobile phase to produce the test solution of 100 µg/mL.

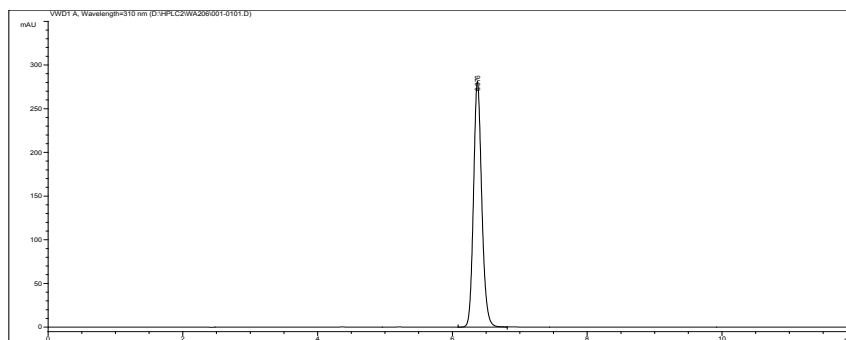
Reference solution: Repeat the procedure using tinidazole CRS to produce the reference solution.

## Chromatographic conditions

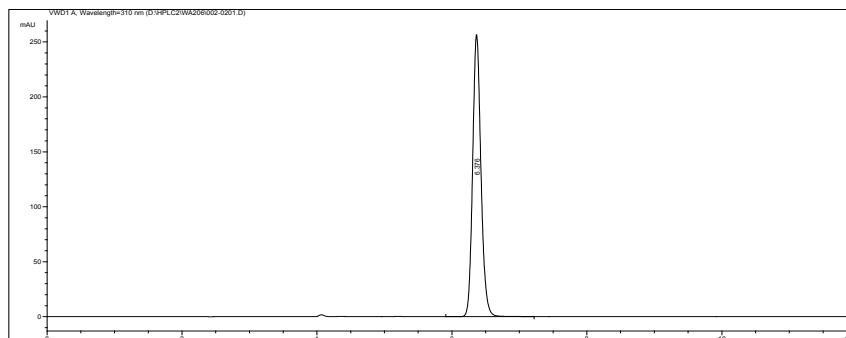
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 3.5 with phosphoric acid) –methanol (75:25)
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA206001-0101



The chromatogram of the test solution--- HPLC2WA206002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tinidazole	6.37	2190.4	10152	/	1.10

# Tinidazole Injection – 替硝唑注射液

Tinidazole (10336-0001) – Method number WA206

## Assay

Test solution: Dilute a quantity of the injection fluid in mobile phase to produce the test solution of 800 µg/mL.

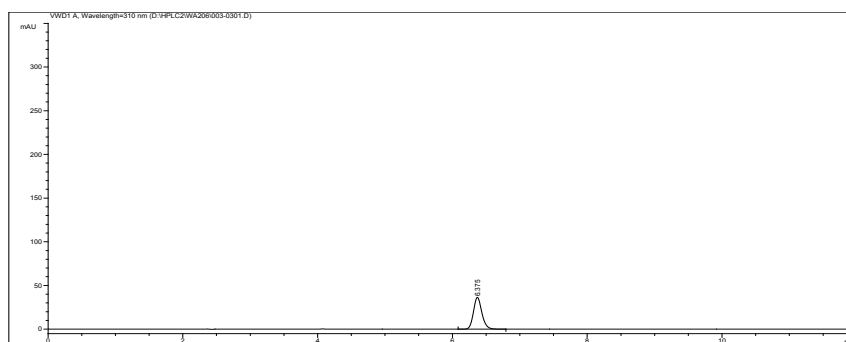
Reference solution: Accurately measure a quantity of the test solution and dilute with mobile phase to produce the reference solution of 8 µg/mL.

## Chromatographic conditions

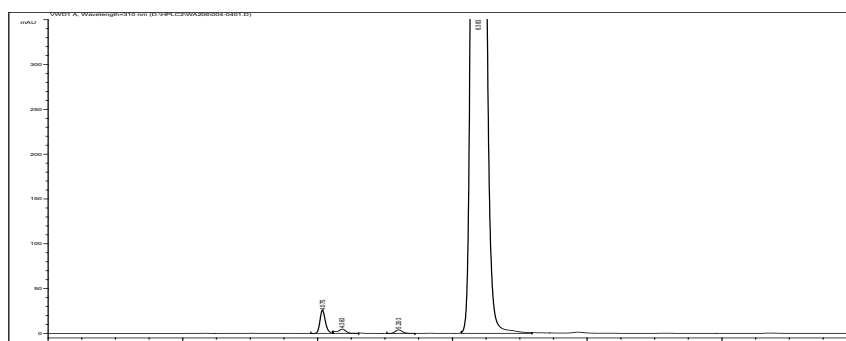
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate (adjust pH to 3.5 with phosphoric acid) - methanol (75:25)
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 310 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA206003-0301



The chromatogram of the test solution--- HPLC2WA206004-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tinidazole	8.86	17723.8	16437	14.5	1.06
Impurity1	5.66	85.2	18821	/	1.08



# Cefalexin – 头孢氨苄

Cefalexin (130408-200209), 7-ADCA, Benzoglycin – Method number WR014

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution of 0.4 mg/mL.

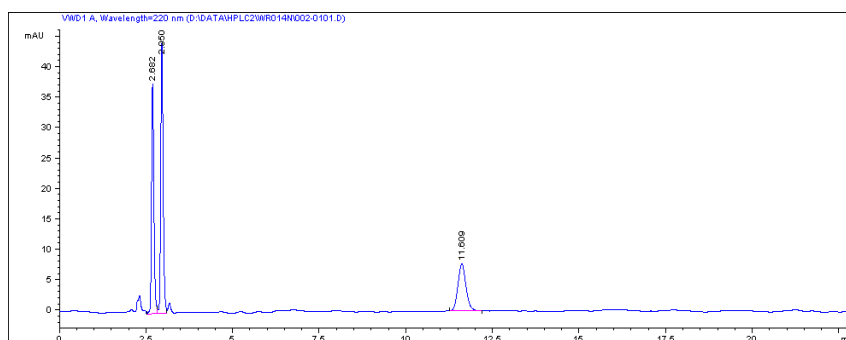
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 4 µg/mL. Dissolve a quantity of 7-aminodesacetoxycephalosp organic acid CRS and α-phenylglycine CRS with a quantity of 0.01 mol/L sodium acetate solution (adjust pH to 5.0 with glacial acetic acid), dilute to produce a mixture of 4 µg/mL each as the reference solution.

## Chromatographic conditions

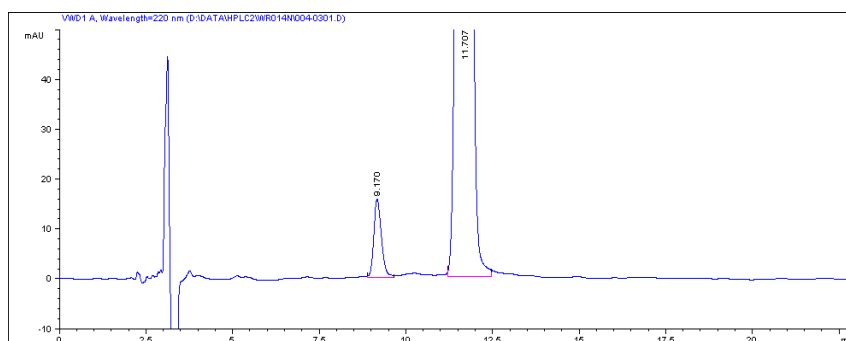
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water:methanol: 3.86 % sodium acetate solution: 4 % acetic acid solution = 742:240:15:3
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2WR014N002-0101



The chromatogram of the test solution --- HPLC1WR014N004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
7-ADCA	2.68	174.4	8635	/	1.24
α-benzoglycin	2.95	207.4	9512	2.3	1.18
Cefalexin	11.61	129.6	12186	31.9	1.11

# Cefalexin Tablets – 头孢氨苄片

## Cefalexin (130408-200209) – Method number WR147

### Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.1 g of cefalexin, in a 100 mL volumetric flask, add a quantity of mobile phase and shake thoroughly to dissolve the cefalexin. Dilute with mobile phase to volume, mix well and filter. Accurately measure 10 mL of the filtrate in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

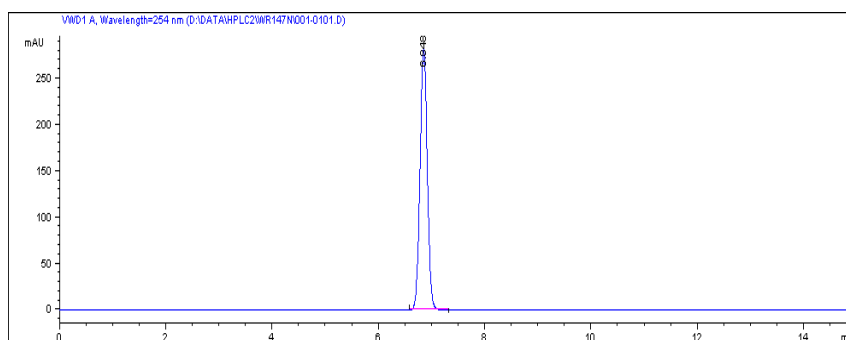
Reference solution: Repeat the procedure using cefalexin CRS to produce the reference solution.

### Chromatographic conditions

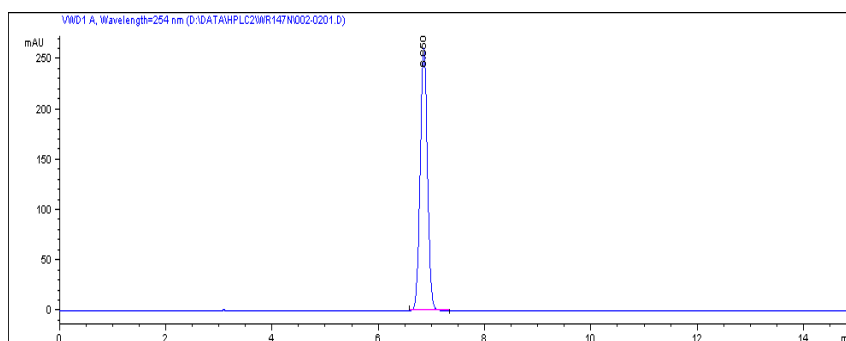
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water: methanol: 3.86 % sodium acetate solution: 4 % acetic acid solution=742:240:15: 3
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR147N\001-0101.D



The chromatogram of the test solution --- HPLC2\WR147N\002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefalexin	6.85	2488.8	11995	/	1.02

# Cefalexin Tablets – 头孢氨苄片

## Cefalexin (130408-200209) – Method number WR147

### Assay

Test solution: Dissolve a quantity of the powder in mobile phase to produce a solution of 0.4 mg/mL, filter and use the filtrate as the test solution.

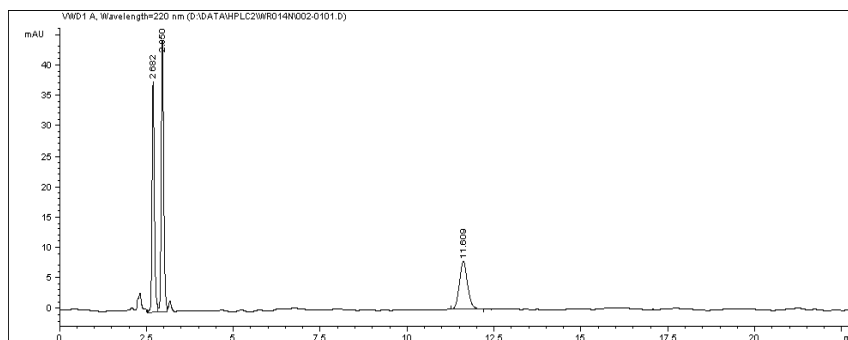
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 4 µg/mL.

### Chromatographic conditions

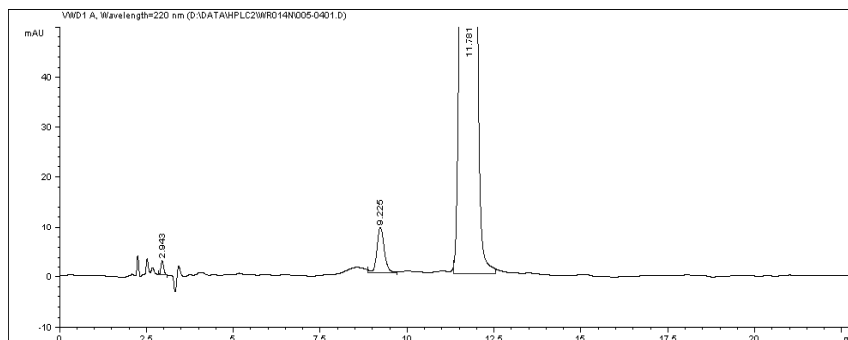
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water:methanol: 3.86 % sodium acetate solution: 4 % acetic acid solution = 742:240:15: 3
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability --HPLC2\WR014N\002-0101



The chromatogram of the test solution --- HPLC2\WR014N\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
7-ADCA	2.68	174.4	8635	/	1.24
α-benzoglycin	2.95	207.4	9512	2.3	1.18
Impurity2	11.61	129.6	12186	31.9	1.11

# Cefdinir – 头孢地尼胶囊

Cefdinir (130502-200401) – Method number WA012

## Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of cefdinir, in a 250 mL amber volumetric flask, dissolve in phosphate BS (pH 7.0), dilute to volume with the mobile phase, mix well, filter and use the filtrate as the test solution.

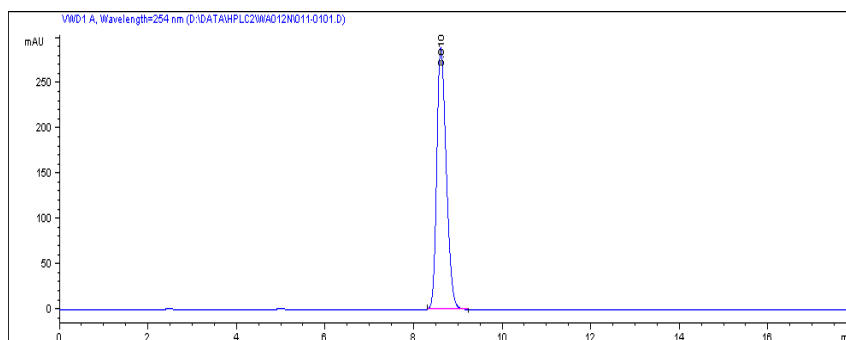
Reference solution: Repeat the procedure using cefdinir CRS to produce the reference solution.

## Chromatographic conditions

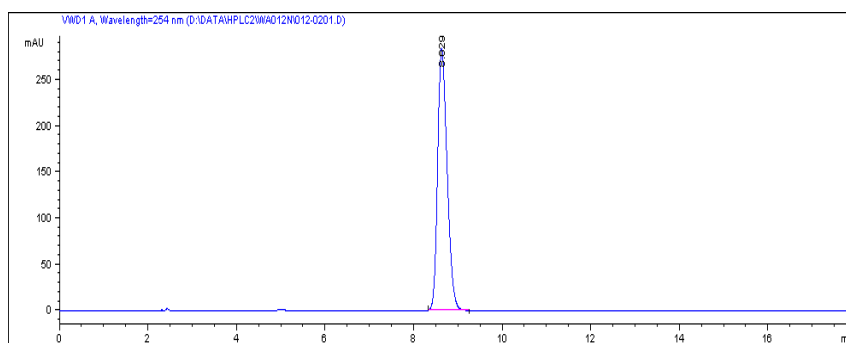
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.4 ml of 0.1 mol/L disodium edetate solution in the mixture of 0.25 % tetramethylammonium hydroxide solution (adjust pH value to 5.5 with phosphoric acid)-acetonitrile-methanol (900:60:40).
- Column temperature: 40 °C
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA012N011-0101



The chromatogram of the test solution --- HPLC2\ WA012N012-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefdinir	8.64	4211.5	7617	/	1.20

# Cefdinir – 头孢地尼

Cefdinir (130502-200401) – Method number WA011

## Assay

Test solution: Dissolve a quantity of the substance in phosphate BS (pH 7.0) and dilute with mobile phase to produce the test solution of 1.5 mg/mL.

Reference solution: Accurately measure 1 mL in a 100 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the reference solution. Dissolve a quantity cefdinir CRS in phosphate BS (pH 7.0), and dilute with mobile phase to produce a solution of 1.5 mg/mL, heat in a water bath for 30 minutes, allow to cool and use for the system suitability test.

### • Mobile phase:

A: 0.4 mL of 0.1 mol/L disodium edetate solution in 1000 mL of 0.25 % tetramethylammonium hydroxide solution (adjust pH value to 5.5 with phosphoric acid)

B: 0.4 mL of 0.1 mol/L disodium edetate solution in the mixture of 0.25 % tetramethylammonium hydroxide solution (adjust pH value to 5.5 with phosphoric acid) - acetonitrile - methanol (500:300:200)

Gradient: 0 min, 95 %A;

2 min, 95 %A; 22 min, 75 %A;

32 min, 50 %A; 37 min, 50 %A;

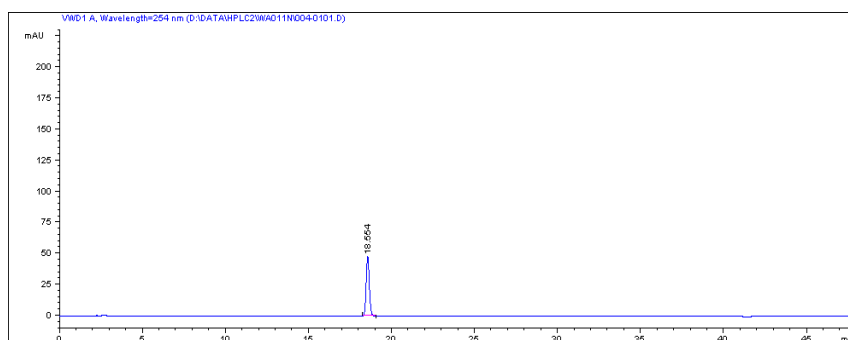
38 min, 95 %A; 48 min, 95 %A

## Chromatographic conditions

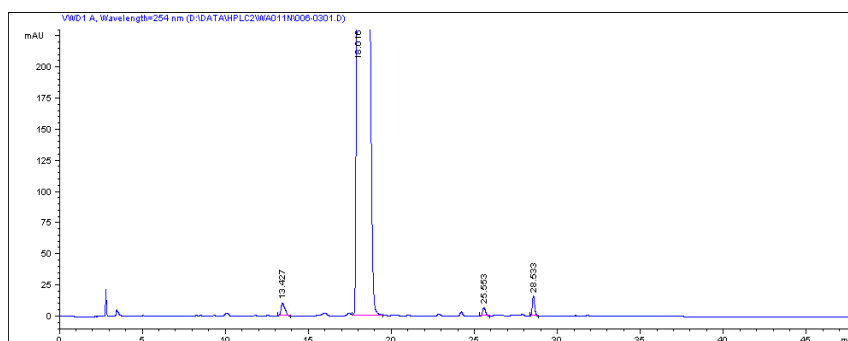
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: see assay
- Column temperature: 40 °C
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

## Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA011N\004-0101



The chromatogram of the test solution --- HPLC2\ WA011N\006-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefdinir	18.02	62334.7	7484	/	/
Cefdinir isomer	28.53	153.8	208112	10.5	1.11

# Cefdinir Capsules – 头孢地尼胶囊

## Cefdinir (130502-200401) – Method number WA012

### Assay

Test solution: Dissolve a quantity of the substance in phosphate BS (pH 7.0) and dilute with mobile phase to produce a solution of 1.5 mg/mL, filter and use the filtrate as the test solution.

Reference solution: Accurately measure a quantity of the test solution and dilute with mobile phase to produce the reference solution of 15 µg/mL.

- Mobile phase:

A: 0.4 mL of 0.1 mol/L disodium edetate solution in 1000 mL of 0.25 % tetramethylammonium hydroxide solution (adjust pH value to 5.5 with phosphoric acid)

B: 0.4 mL of 0.1 mol/L disodium edetate solution in the mixture of 0.25 % tetramethylammonium hydroxide solution (adjust pH value to 5.5 with phosphoric acid) - acetonitrile - methanol (500:300:200)

Gradient: 0 min, 95 %A;

2 min, 95 %A; 22 min, 75 %A;

32 min, 50 %A; 37 min, 50 %A;

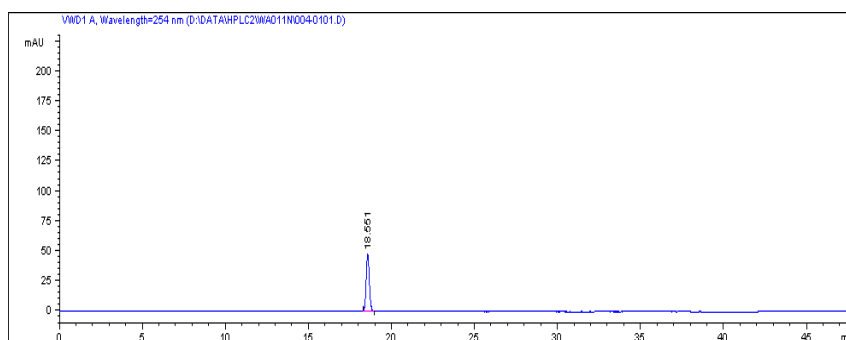
38 min, 95 %A; 48 min, 95 %A

### Chromatographic conditions

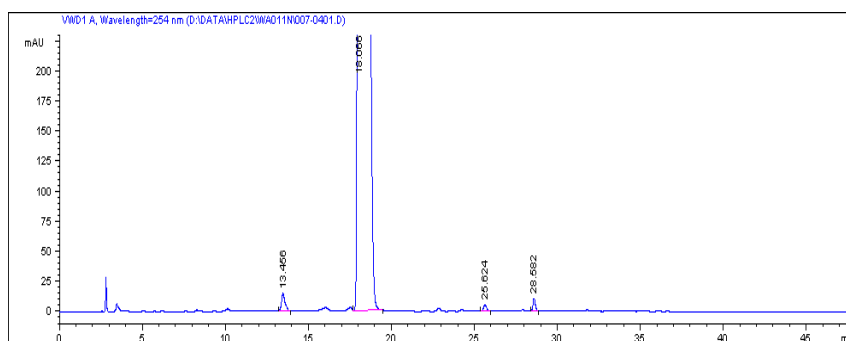
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: see assay
- Column temperature: 40 °C
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA011N004-0101



The chromatogram of the test solution --- HPLC2\ WA011N006-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefdinir	18.07	59988.7	7676	/	/
Cefdinir isomer	28.58	100.2	213493	10.5	1.10

# Cefuroxime Sodium – 头孢呋辛钠

## Cefuroxime (130493-200102) – Method number WR008

### Assay

Test solution: Dissolve a quantity of the substance in water to produce the test solution of 0.5 mg/mL.

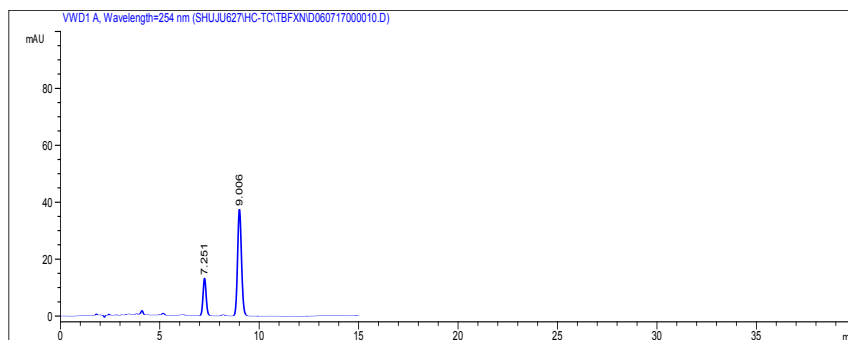
Reference solution: Dissolve a quantity of the substance in water to produce the reference solution of 5 µg/mL. Dissolve and dilute a quantity of cefuroxime CRS in water to produce a solution of 100 µg/mL. Heat in a water bath at 60 °C for 10 minutes, allow to cool and use for the system suitability test.

### Chromatographic conditions

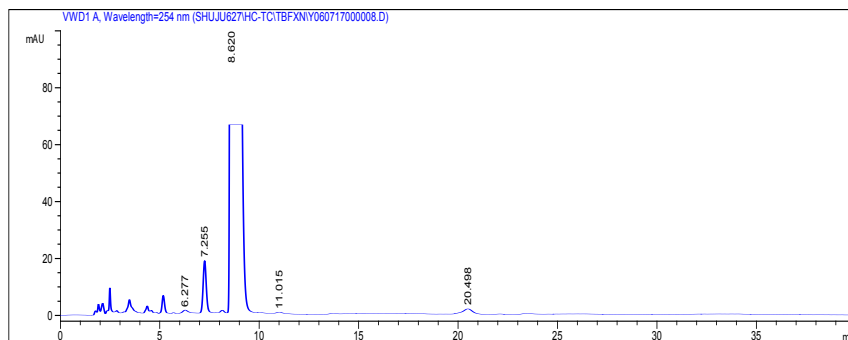
- Column: Agilent TC-C18 4.6x250 mm, 5 µm (518935-902)
- Mobile phase: 0.1 mol/L sodium acetate solution (adjust pH to 3.0 with acetic acid) :acetonitrile = 86:14
- Flow rate: 1 mL/min
- Injection volume: 20 µL
- Column temperature: 25 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability---HPLC2\WR008



The chromatogram of the test solution--- HPLC2\WR008

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Degraded product	7.25		10503	/	1.07
Cefuroxime	9.01		12037	3.06	1.10

# Cefuroxime Axetil Capsules – 头孢呋辛酯胶囊

Cefuroxime Axetil (0492-200001) – Method number WR011

## Assay

Test solution: Dissolve an accurately weighed quantity of the finely powdered and well-mixed contents, equivalent to about 125 mg of cefuroxime, in 25 mL of methanol by shaking intensively. Dilute with mobile phase to 100 mL, mix well and filter. Transfer 5 mL of the filtrate to a 25 mL volumetric flask, dilute with mobile phase to volume and use as the test solution.

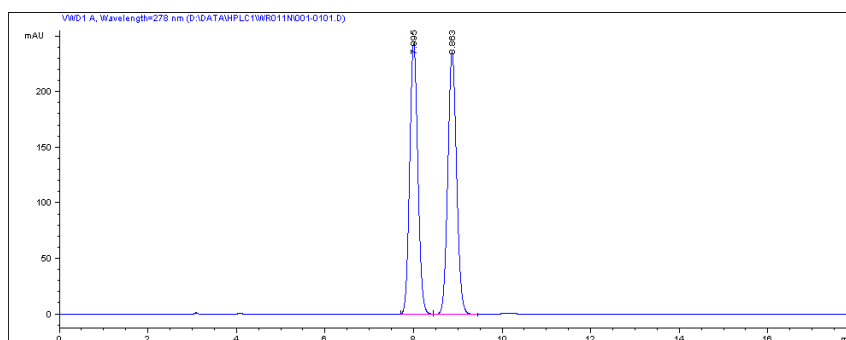
Reference solution: Repeat the procedure using cefuroxime axetil CRS to produce the reference solution.

## Chromatographic conditions

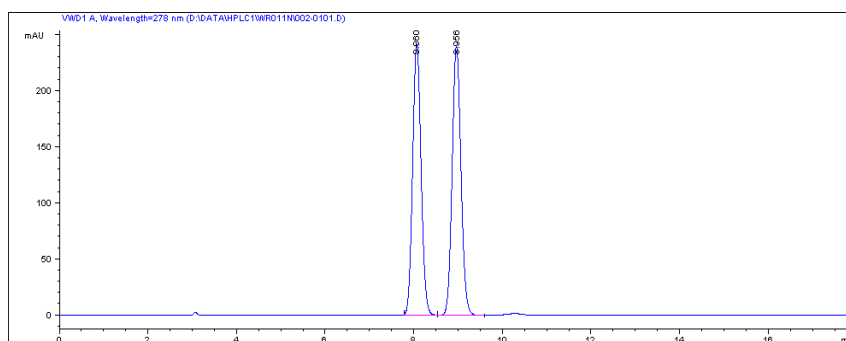
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.2 mol/L ammonium dihydrogen phosphate solution-methanol (50:50).
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 278 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR011N001-0101



The chromatogram of the test solution --- HPLC1\ WR011N002-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefuroxime Axetil B	8.06	3235.2	8459	/	1.07
Cefuroxime Axetil A	8.96	3347.7	9745	2.5	1.07



# Cefuroxime Axetil Capsules – 头孢呋辛酯胶囊

Cefuroxime Axetil (130493-200102) – Method number WR011

## Assay

Test solution: Dissolve an accurately weighed quantity of the finely powdered and well-mixed contents, equivalent to about 125 mg of cefuroxime, in 25 mL of methanol by shaking intensively. Dilute with mobile phase to 100 mL, mix well and filter. Transfer 5 mL of the filtrate to a 25 mL volumetric flask, dilute with mobile phase to volume and use as the test solution.

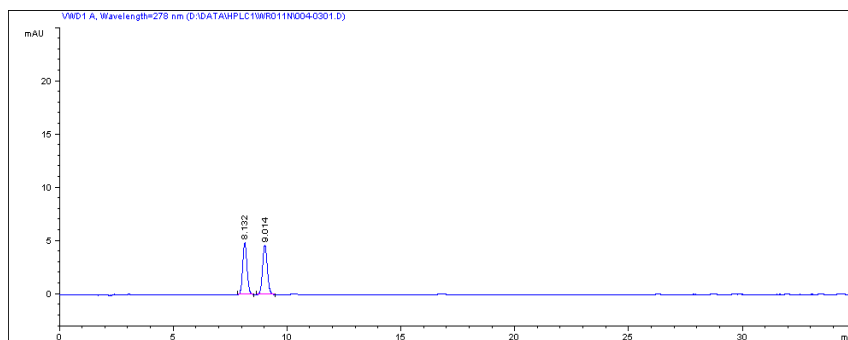
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 2.5 µg/mL.

## Chromatographic conditions

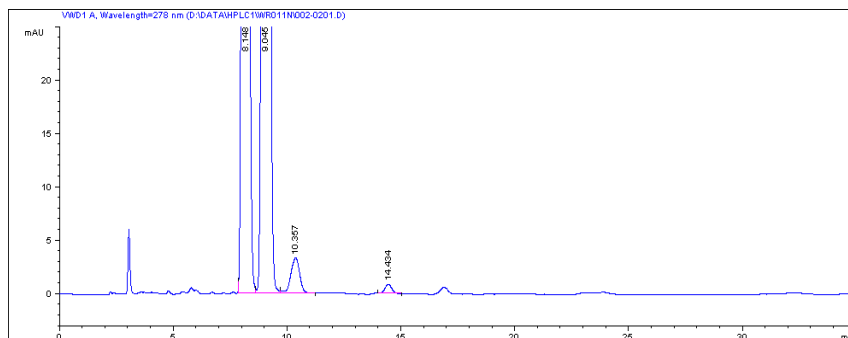
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.2 mol/L ammonium dihydrogen phosphate solution-methanol (50: 50)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 278 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution--- HPLC1\WR011\N004-0301



The chromatogram of the test solution--- HPLC1\WR011\N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefuroxime Axetil B	8.15	6427.5	9142	/	1.07
Cefuroxime Axetil A	9.05	6655.1	8899	2.5	1.06
Impurity1	10.36	89.6	3411	2.4	0.87
Impurity2	14.14	20.9	10001	6.4	1.02

# Cefuroxime Axetil Tablets – 头孢呋辛酯片

## Cefuroxime Axetil (130493-200102) – Method number WR01

### Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to about 125 mg of cefuroxime, in 25 mL of methanol by shaking intensively. Dilute with mobile phase to 100 mL, mix well and filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with mobile phase to volume and use as the test solution.

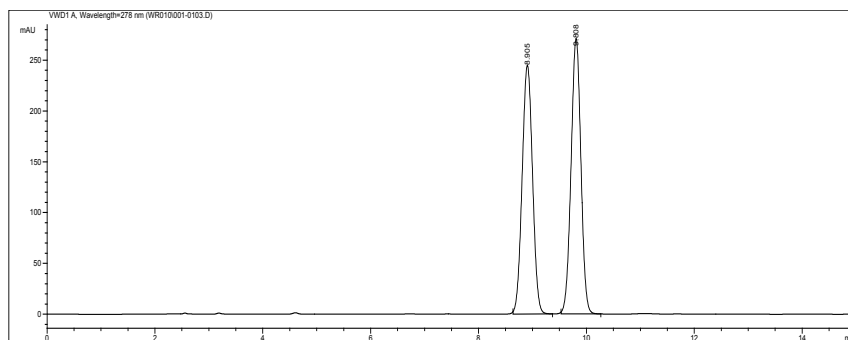
Reference solution: Repeat the procedure using cefuroxime axetil CRS to produce the reference solution.

### Chromatographic conditions

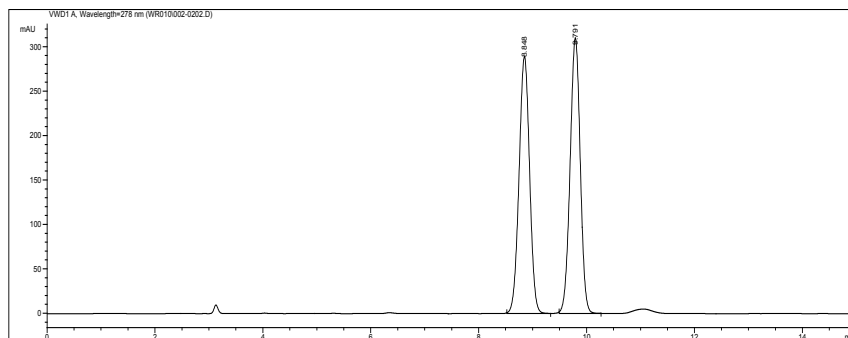
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.2 mol/L ammonium dihydrogen phosphate solution-methanol (50: 50)
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 278 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC1\WR01\001-0103.D



The chromatogram of the test solution --- HPLC1\WR01\002-0202.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefuroxime Axetil B	8.85	3923.5	9090	/	1.00
Cefuroxime Axetil A	9.79	4056.3	12195	2.6	0.98

# Cefuroxime Axetil Tablets – 头孢呋辛酯片

## Cefuroxime Axetil (130493-200102) – Method number WR010

### Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to about 125 mg of cefuroxime in 25 mL of methanol by shaking intensively. Dilute with mobile phase to 100 mL, mix well and filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with mobile phase to volume and use as the test solution.

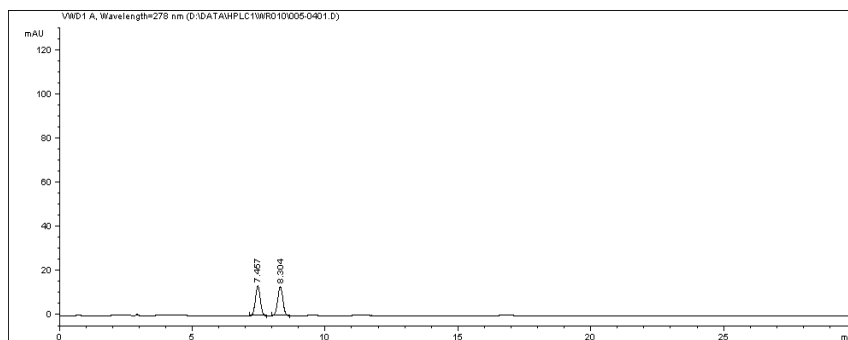
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 2.5 µg/mL.

### Chromatographic conditions

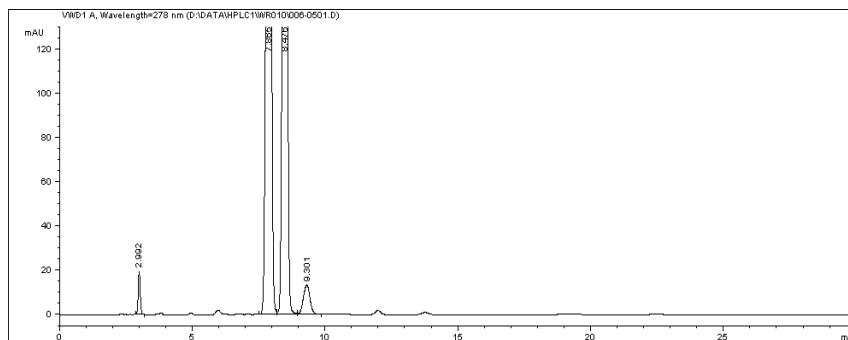
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.2 mol/L ammonium dihydrogen phosphate solution-methanol (50: 50)
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 278 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability---HPLC1\WR010\005-0401.D



The chromatogram of the test solution--- HPLC1\WR010\006-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefuroxime Axetil B	7.87	6535.6	13635	23.5	0.99
Cefuroxime Axetil A	8.48	6964.4	20564	2.4	1.00
Impurity1	2.99	103.1	7460	/	1.09
Impurity2	9.30	231.2	6606	2.3	1.01

# Cefaclor – 头孢克洛

Cefaclor (30481-200102) – Method number WR007

## Assay

Test solution: Dissolve an accurately weighed quantity of about 50 mg in a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) in a 10 mL volumetric flask (treat ultrasonically, if necessary, but do not allow to get too hot), dilute to volume, shake well and use as the test solution.

Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) to volume, mix well and use as the reference solution.

- Mobile phase:

A: 0.78 % solution of sodium dihydrogen phosphate (dissolve 7.8 g of sodium dihydrogen phosphate in water and dilute to 1000 mL, adjust pH to 4.0 with phosphoric acid)

B: 0.78 % solution of sodium dihydrogen phosphate (pH 4.0)-acetonitrile(55:45)

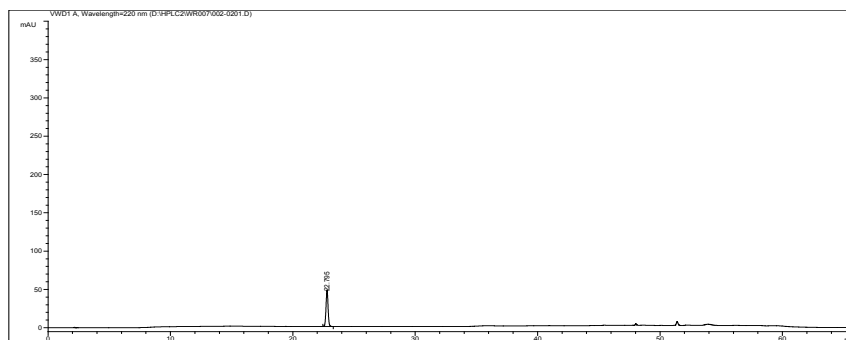
Gradient: 0 min, 5 %B; 30 min, 25 %B; 45 min, 100 %B; 55 min, 100 %B; 56 min, 5 %B; 66 min, 5 %B

## Chromatographic conditions

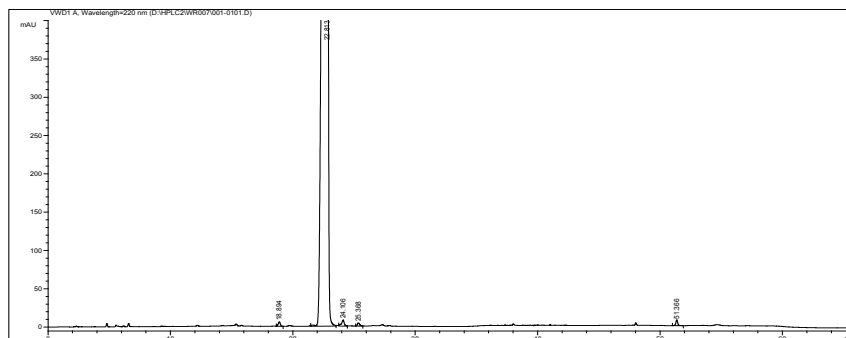
- Column: ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: see assay
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR007002-0201.D



The chromatogram of the test solution--- HPLC2WR007001-0101.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefaclor	22.81	57076.2	21192	8.3	/
¶S-3-Cefaclor	18.89	67.1	59179	/	0.96
Impurity1	24.11	122.2	81304	2.7	0.82
Impurity2	25.37	51.5	102113	3.8	1.34
Impurity3	51.37	82.7	552952	87.4	1.05

# Cefaclor for Suspension – 头孢克洛干混悬剂

Cefaclor (30481-200102) – Method number WR137

## Assay

Test solution: Dissolve an accurately weighed quantity of about 50 mg in a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) in a 10 mL volumetric flask (treat ultrasonically, if necessary, but do not allow to get too hot), dilute to volume, shake well and use as the test solution.

Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) to volume, mix well and use as the reference solution.

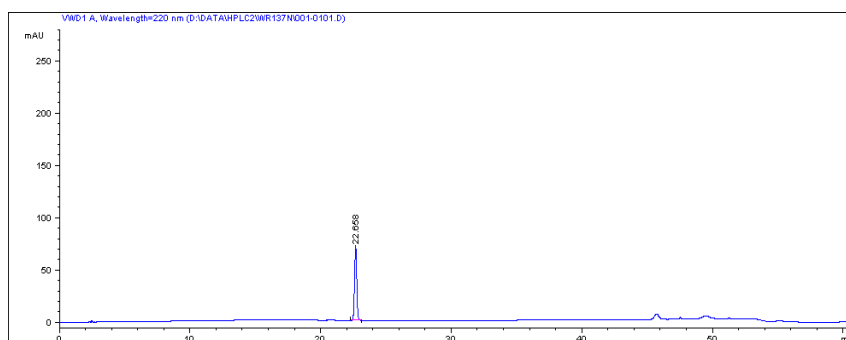
- Mobile phase:  
A: 0.78 % solution of sodium dihydrogen phosphate (dissolve 7.8g of sodium dihydrogen phosphate in water and dilute to 1000 mL, adjust pH to 4.0 with phosphoric acid)  
B: 0.78 % solution of sodium dihydrogen phosphate (pH4.0) : acetonitrile (55:45)  
Gradient: 0 min, 5 %B;  
30 min, 25 %B; 45 min, 100 %B;  
55 min, 100 %B; 56 min, 5 %B;  
66 min, 5 %B

## Chromatographic conditions

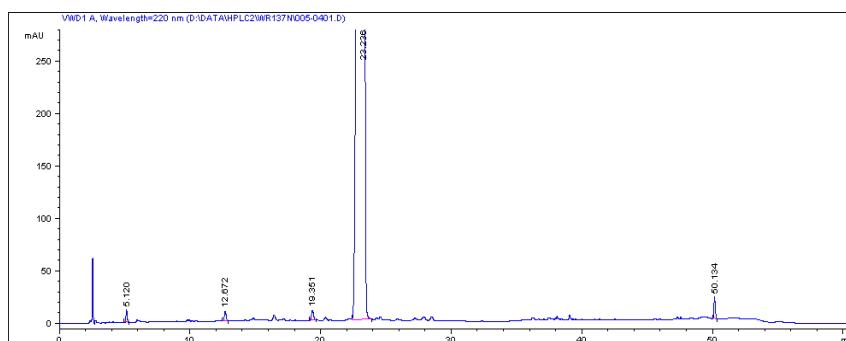
- Column : ZORBAX SB-C18  
4.6×250 mm, 5 μm (990967-902)
- Mobile phase: see assay
- Flow rate: 1.0 mL/ min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WR137N001-0101.D



The chromatogram of the test solution --- HPLC2WR137N005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	5.12	75.9	14318	/	1.06
Impurity2	12.67	88.6	42911	36.0	1.09
1S-3-Cefaclor	18.89	67.1	59179	/	1.15
Cefaclor	23.24	68256.5	18883	7.9	/
Impurity3	50.13	152.9	/	/	1.13

# Cefaclor Capsules – 头孢克洛胶囊

## Cefaclor (30481-200102) – Method number WR139

### Assay

Test solution: Dissolve an accurately weighed quantity of about 50 mg in a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) in a 10 mL volumetric flask (treat ultrasonically, if necessary, but do not allow to get too hot), dilute to volume, shake well and use as the test solution.

Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) to volume, mix well and use as the reference solution.

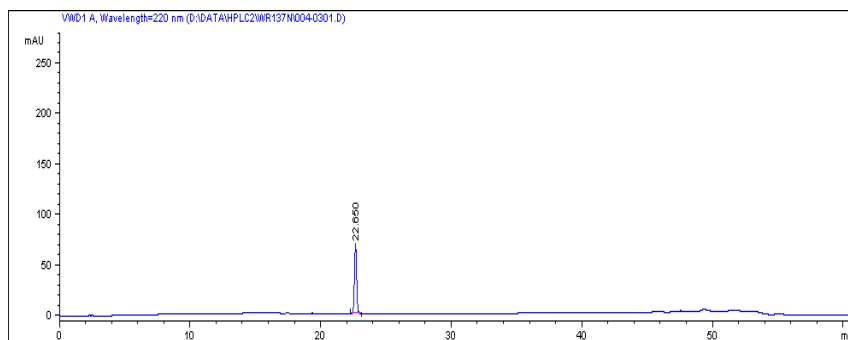
- Mobile phase:  
A: 0.78 % solution of sodium dihydrogen phosphate (dissolve 7.8g of sodium dihydrogen phosphate in water and dilute to 1000 mL, adjust pH to 4.0 with phosphoric acid)  
B: 0.78 % solution of sodium dihydrogen phosphate (pH4.0) : acetonitrile (55:45)  
Gradient: 0 min, 5 %B;  
30 min, 25 %B; 45 min, 100 %B;  
55 min, 100 %B; 56 min, 5 %B;  
66 min, 5 %B

### Chromatographic conditions

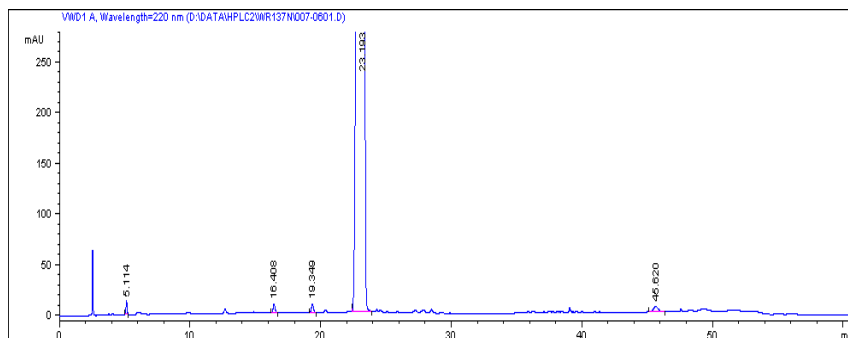
- Column : ZORBAX SB-C18  
4.6×250 mm, 5 μm (990967-902)
- Mobile phase: see assay
- Flow rate: 1.0 mL/ min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR137N004-0301.D



The chromatogram of the test solution--- HPLC2WR137N007-0601.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	5.11	85.9	14635	/	1.07
Impurity2	16.41	90.9	54776	50.2	1.07
1S-3-Cefaclor	19.35	101.3	65497	10.1	1.09
Cefaclor	23.19	67884.4	18365	7.8	/
Impurity3	45.62	130.0	76482	33.3	1.38

# Cefaclor Tablets – 头孢克洛片

## Cefaclor (30481-200102) – Method number WR138

### Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to about 50 mg of cefaclor, in a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) in a 10 mL volumetric flask (treat ultrasonically, if necessary, but do not allow to get too hot), dilute to volume, shake well and use as the test solution.

Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with a 0.27 % solution of sodium dihydrogen phosphate (pH 2.5) to volume, mix well and use as the reference solution.

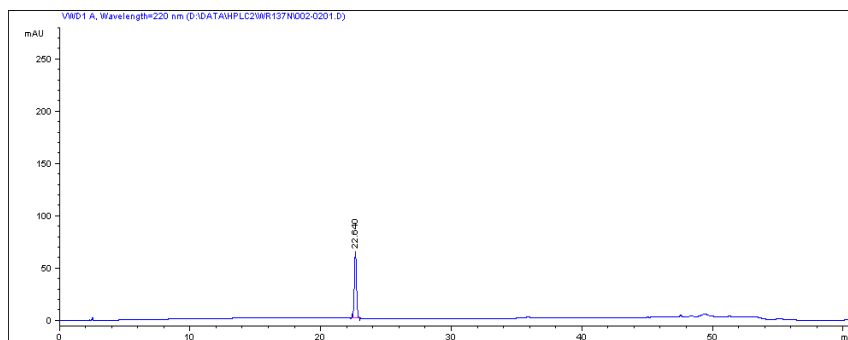
- Mobile phase:  
A: 0.78 % solution of sodium dihydrogen phosphate (dissolve 7.8g of sodium dihydrogen phosphate in water and dilute to 1000 mL, adjust pH to 4.0 with phosphoric acid)  
B: 0.78 % solution of sodium dihydrogen phosphate (pH4.0) : acetonitrile (55:45)  
Gradient: 0 min, 5 %B;  
30 min, 25 %B; 45 min, 100 %B;  
55 min, 100 %B; 56 min, 5 %B;  
66 min, 5 %B

### Chromatographic conditions

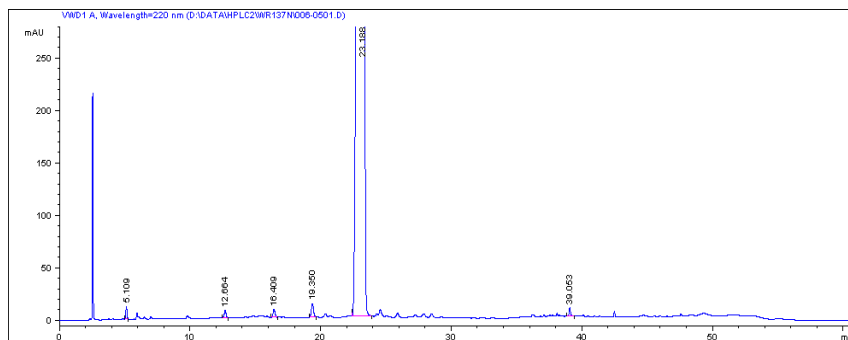
- Column : ZORBAX SB-C18  
4.6×250 mm, 5 µm (990967-902)
- Mobile phase: see assay
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR137N002-0201.D



The chromatogram of the test solution--- HPLC2WR137N006-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	5.11	81.4	14259	/	1.07
Impurity2	12.66	67.7	41912	36.0	1.12
Impurity3	16.41	76.8	55874	14.2	1.07
β-S-Cefaclor	19.35	153.8	65501	10.1	1.10
Cefaclor	23.19	68236.8	17098	7.6	/

# Cefradine – 头孢拉定

Cefradine (130427-200306) – Method number WR140

## Assay

Test solution: Dissolve a quantity in mobile phase to produce the test solution of 1 mg/mL.

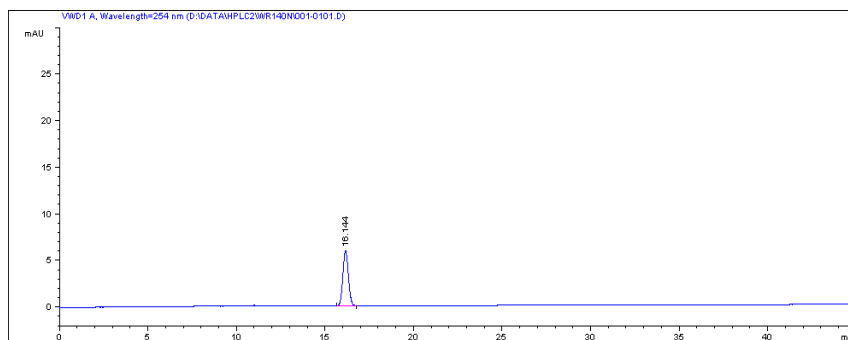
Reference solution: Dissolve a quantity in mobile phase to produce the reference solution of 5 µg/mL.

## Chromatographic conditions

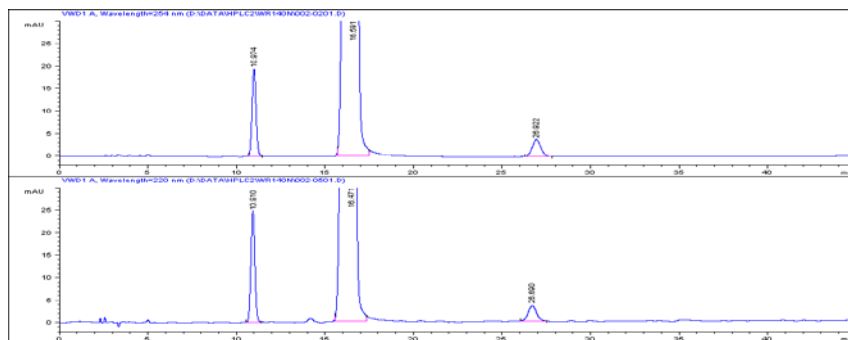
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water: methanol: 3.86 % sodium acetate solution: 4 % solution of acetic acid = 1564:400:30:6
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254/220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR140\N001-0101



The chromatogram of the test solution --- HPLC2\WR140\N\002-0201\002-0501

Constituents (test solution 254 nm)	Ret Time ( min )	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	10.97	305.1	11560	/	1.06
Cefradine	16.59	26280.1	7649	9.6	0.72
Impurity2	26.92	126.0	15172	12.6	1.06



# Cefradine Capsules – 头孢拉定胶囊

## Cefradine (130427-200306) – Method number WR142

### Assay

Test solution: Dissolve an accurately weighed quantity of the powdered and well-mixed contents in mobile phase to produce the test solution of 1 mg/mL.

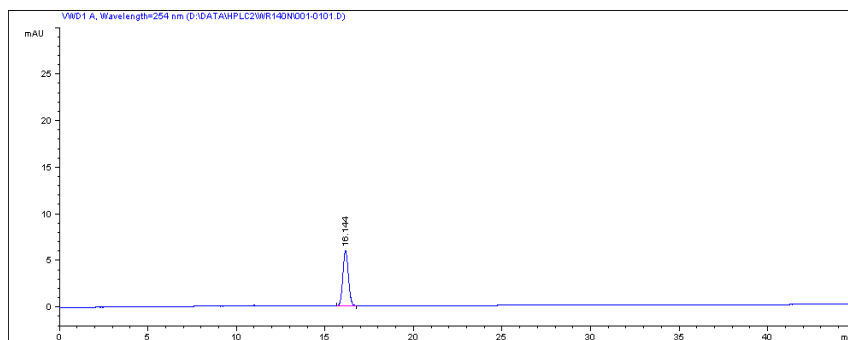
Reference solution: Dissolve an accurately weighed quantity of the powdered and well-mixed contents in mobile phase to produce the reference solution of 5 µg/mL.

### Chromatographic conditions

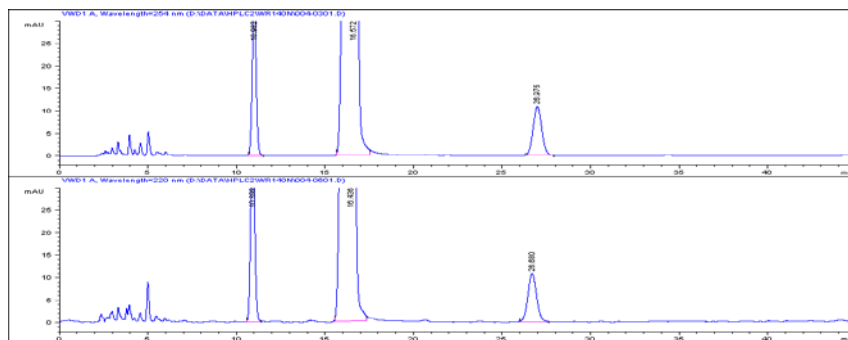
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water: methanol: 3.86 % sodium acetate solution: 4 % solution of acetic acid = 1564:400:30:6
- Flow rate: 1.0 mL/ min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254/220 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR140N\001-0101



The chromatogram of the test solution --- HPLC2\WR140N\004-0301

Constituents (test solution)	Ret Time ( min )	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	10.98	532.3	11814	/	1.05
Cefradine	16.57	24582.4	7468	9.5	0.73
Impurity2	26.98	373.1	14673	12.5	1.05

# Cefathiamidine – 头孢硫脒

Cefathiamidine (130523-200201) – Method number WA014

## Assay

Test solution: Add mobile phase to a quantity of the substance to produce the test solution of 0.5 mg/mL.

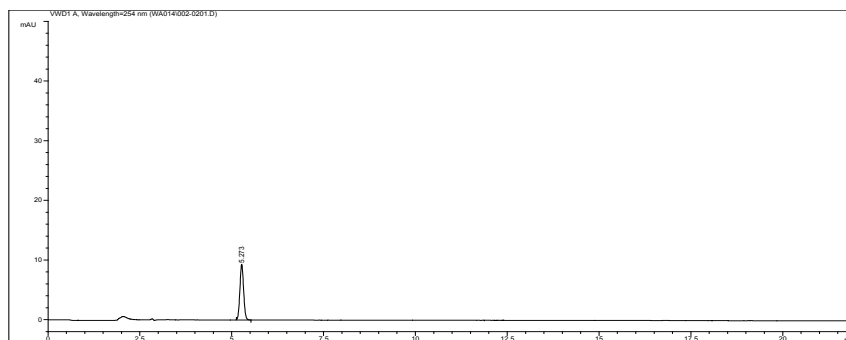
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution containing 5 µg/mL.

## Chromatographic conditions

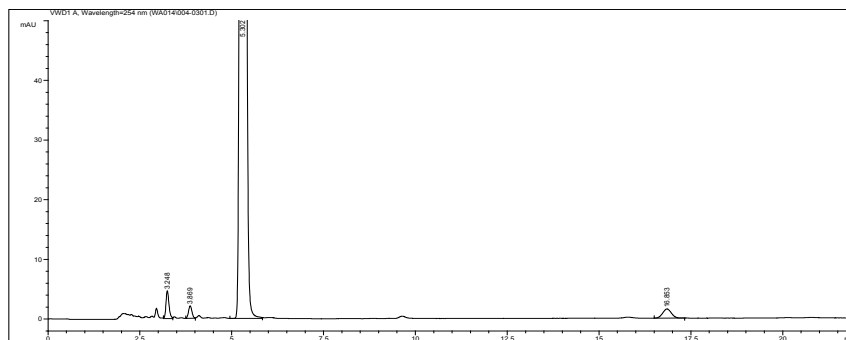
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: BS (dissolve 2.76 g of anhydrous disodium hydrogen phosphate and 1.29 g of citric acid in 1000 ml of water) : acetonitrile = 80:20
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA014\002-0201



The chromatogram of the test solution--- HPLC1\WA014\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefathiamidine	5.30	5797.4	11164	7.74	1.08
Impurity1	3.25	26.7	8194	/	1.29
Impurity2	3.87	13.5	8378	3.97	1.09
Impurity3	16.85	24.9	23780	36.2	1.03

# Cefoperazone – 头孢哌酮

Cefoperazone (130420-200304), Cefoperazone degraded product B (130428-200102), Cefoperazone isomer S (0412-9601) – Method number WR144

## Assay

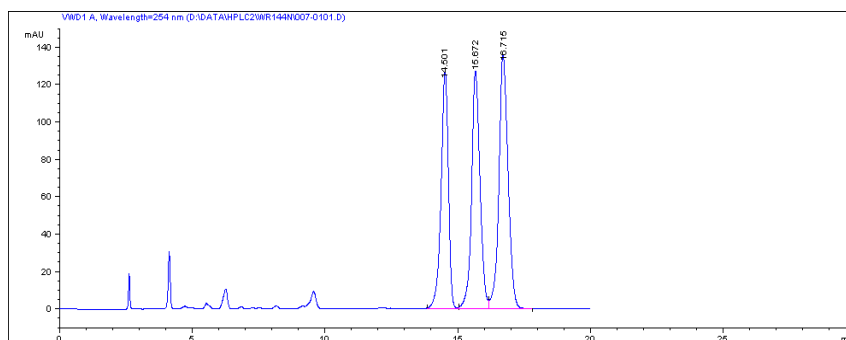
Dissolve a quantity of cefoperazone CRS, cefoperazone degraded product B CRS and cefoperazone isomer-S CRS in a small volume of phosphate BS. Dilute with mobile phase to produce a mixture of 0.2 mg/mL of each component and use for the system suitability test.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-Aq 4.6x250mm, 5um (880975-914)
- Mobile phase: triethylamine acetic acid solution(dissolve 1.4 mL of triethylamine and 0.57 mg of glacial acetic acid in 8 mL of water, mix well, dilute 6 µL with water to 410 mL, mix well, adjust pH to 3.0±0.2 with glacial acetic acid): acetonitrile = 82:18
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2WR144N007-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefoperazone degraded product B	14.50	2448.8	13291	/	0.87
Cefoperazone	15.67	2811.2	12869	2.2	1.00
Cefoperazone isomer S	16.72	3266.4	11682	1.8	0.97

# Cefoperazone Sodium – 头孢哌酮钠

Cefoperazone (130420-200304), Cefoperazone B (130428-200102),

Cefoperazone S (0412-9601) – Method number WR012

## Assay

Test solution: Accurately weigh about 50 mg of the substance in a 100 mL volumetric flask, dissolve in mobile phase, dilute to volume, mix well and use as the test solution.

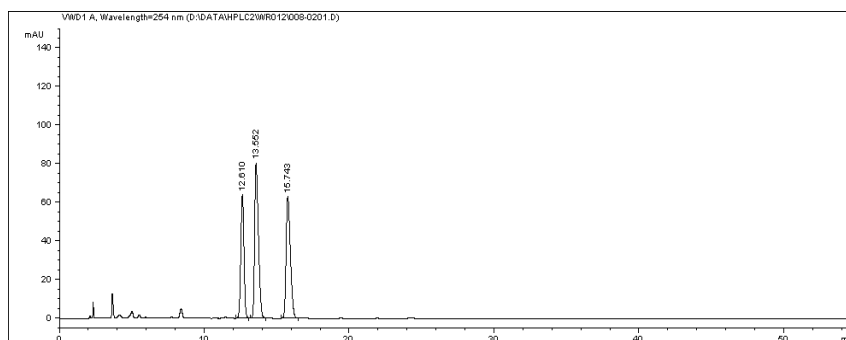
Reference solution: Dissolve a quantity of cefoperazone CRS, cefoperazone B CRS (dissolved in acetonitrile) and cefoperazone-S CRS in a quantity of phosphate BS (mix 39.0 mL of 0.2 mol/L sodium dihydrogen phosphate solution and 61.0 mL of 0.2 mol/L disodium hydrogen phosphate solution, adjust pH to 7.0 with phosphoric acid), dilute with mobile phase to produce a mixture of 0.2 mg/mL of each component and use as the reference solution.

## Chromatographic conditions

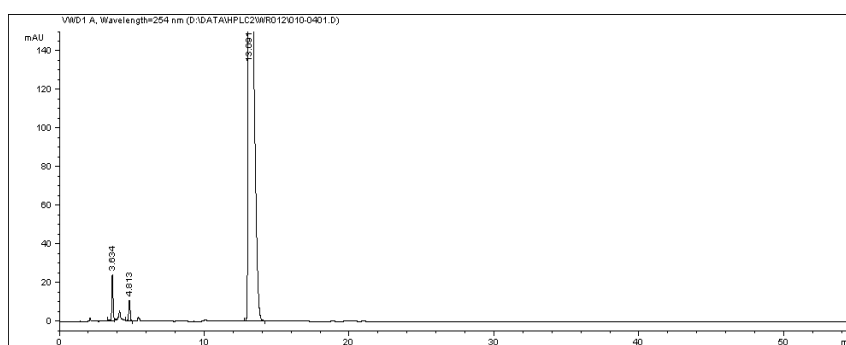
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: triethylamine acetate solution (dissolve 1.4 mL of triethylamine and 0.57 mL of glacial acetic acid in 8 mL of water, mix well, dilute 6 µL with water to 410 mL, mix well, adjust pH to 3.0±0.2 with glacial acetic acid): acetonitrile = 83:17
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2WR012008-0201



The chromatogram of the test solution ---HPLC2WR012010-0401

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>i</sub>
cefoperazone B	12.61	964.7	16232	/	1.021
cefoperazone	13.57	1458.6	12878	2.20	1.054
cefoperazone S	15.76	1293.8	13615	4.29	/

# Cefadroxil – 头孢羟氨苄

Cefadroxil (0431-9501) – Method number WR015

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase, shake to dissolve the cefadroxil, dilute with mobile phase to produce the test solution of 0.7 mg/mL.

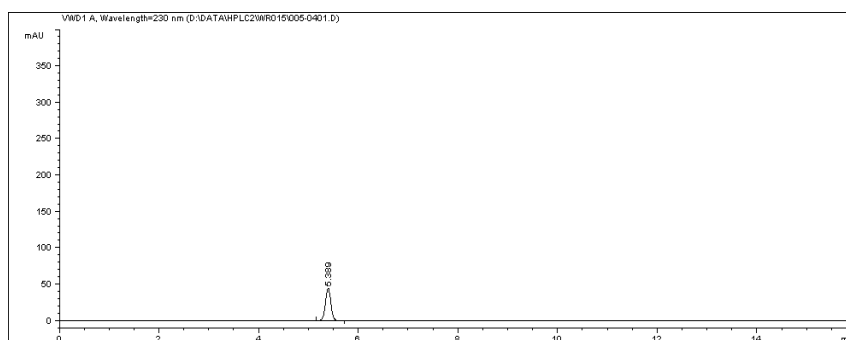
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 7 µg/mL.

## Chromatographic conditions

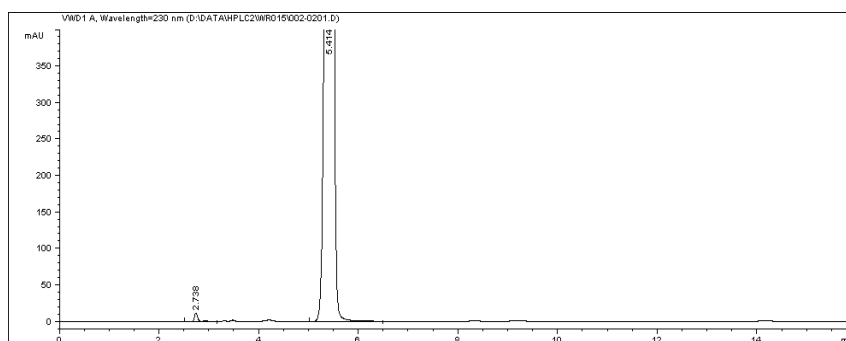
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile: 0.05 mol/L potassium dihydrogen phosphate solution (adjust pH to 5.5 with 10 mol/L sodium hydroxide) = 5:95
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR015005-0401



The chromatogram of the test solution--- HPLC2WR015002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefadroxil	5.42	28705.3	11505	17.2	0.94
Impurity1	2.74	50.8	9897	/	1.16

/

# Cefadroxil Capsules – 头孢羟氨苄胶囊

Cefadroxil (0431-9501) – Method number WR016

## Assay

Test solution: Dissolve a quantity of the contents in mobile phase, shake to dissolve the cefadroxil, dilute with mobile phase to produce a solution of 0.7 mg/mL, filter and use the filtrate as the test solution.

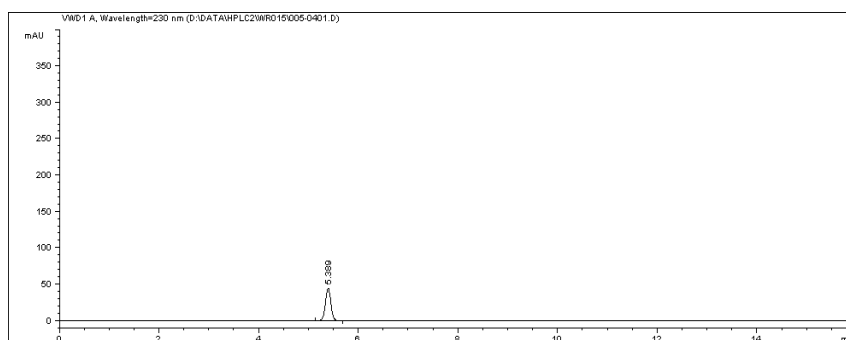
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 7 µg/mL.

## Chromatographic conditions

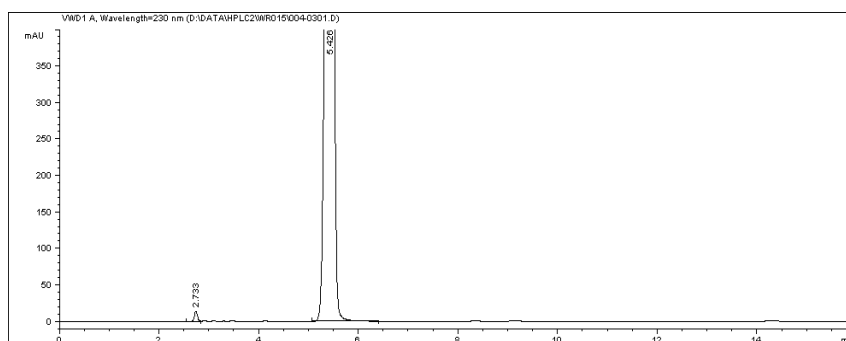
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile: 0.05mol/L potassium dihydrogen phosphate solution (adjust pH to 5.5 with 10 mol/L sodium hydroxide) = 5:95
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WR015\005-0401.D



The chromatogram of the test solution--- HPLC1\WR015\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefadroxil	5.42	28949.6	11054	17.0	0.93
Impurity	2.73	10.61	10137	/	1.07

/

# Cefadroxil Granules – 头孢羟氨苄颗粒

Cefadroxil (0431-9501) – Method number WR017

## Assay

Test solution: Dissolve a quantity of the powder in mobile phase, shake to dissolve the cefadroxil, dilute with mobile phase to produce a solution of 0.7 mg/mL, filter and use the filtrate as the test solution.

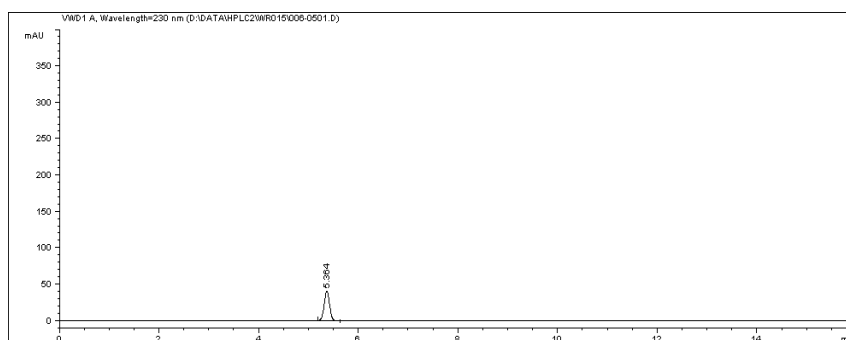
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 7 µg/mL.

## Chromatographic conditions

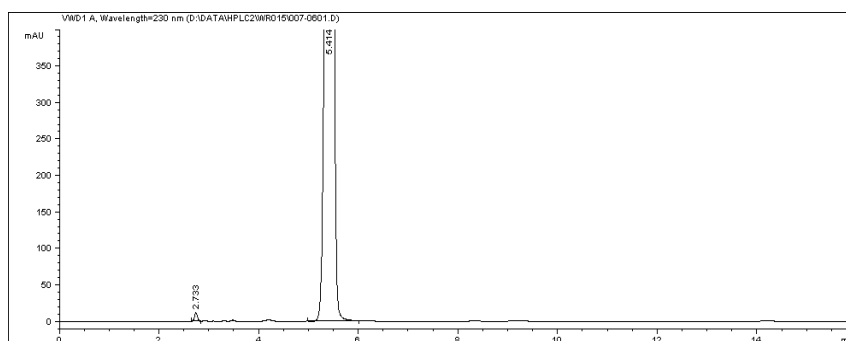
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: acetonitrile: 0.05 mol/L potassium dihydrogen phosphate solution (adjust pH to 5.5 with 10 mol/L sodium hydroxide) = 5:95
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR015006-0501.D



The chromatogram of the test solution--- HPLC2WR015007-0601.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefadroxil	5.41	28727.3	9456	16.2	0.96
Impurity	2.73	10.60	10134	/	1.17

# Ceftriaxone Sodium – 头孢曲松钠

## Ceftriaxone Sodium (SIGMA) – Method number WR006

### Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution of 0.22 mg/mL.

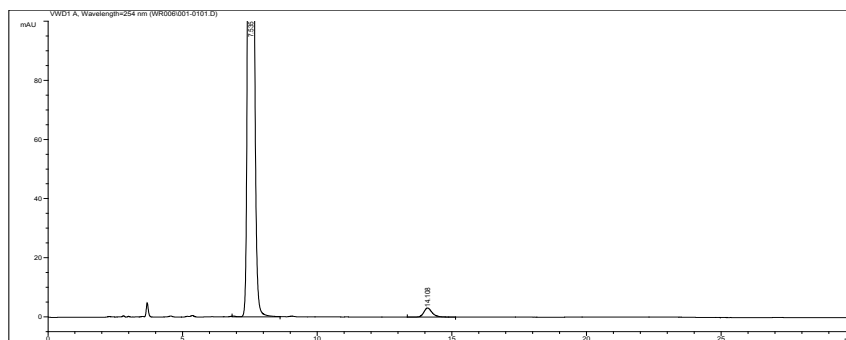
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 2.2 µg/mL. Irradiate a quantity of the substance with UV light for 24 hours and dissolve in mobile phase to produce a solution of 0.22 mg/mL for the system suitability test.

### Chromatographic conditions

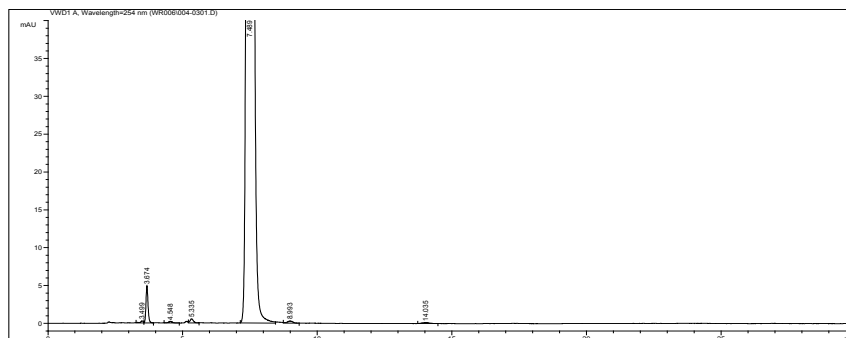
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.02 mol/L n-octylamine-acetonitrile (73:27), adjust pH to 6.5 with phosphoric acid
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC1\WR006\001-0101.D



The chromatogram of the test solution--- HPLC1\WR006\004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ceftriaxone	7.50	5375.2	10768	/	1.10
Ceftriaxone-trans	14.0	2.5	11672	11.6	1.10



# Ceftezole Sodium – 头孢替唑钠

## Ceftezole (130510-200301) – Method number WA013

### Assay

Test solution: Dissolve a quantity of the substance in water to produce the test solution containing 1 mg/mL.

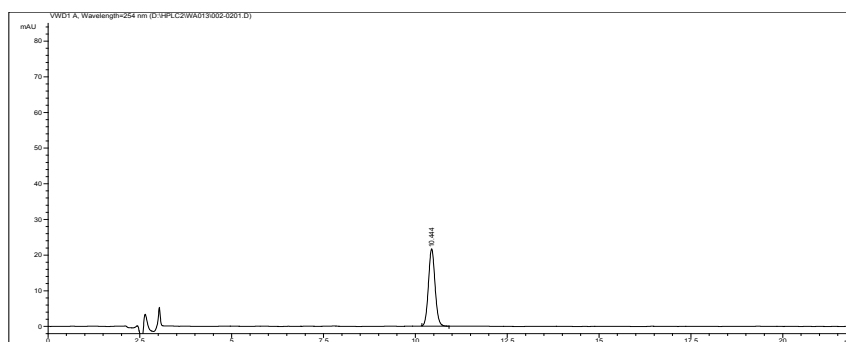
Reference solution: Dilute an accurately measured quantity of the test solution in mobile phase to produce reference solution containing 10 mg/mL.

### Chromatographic conditions

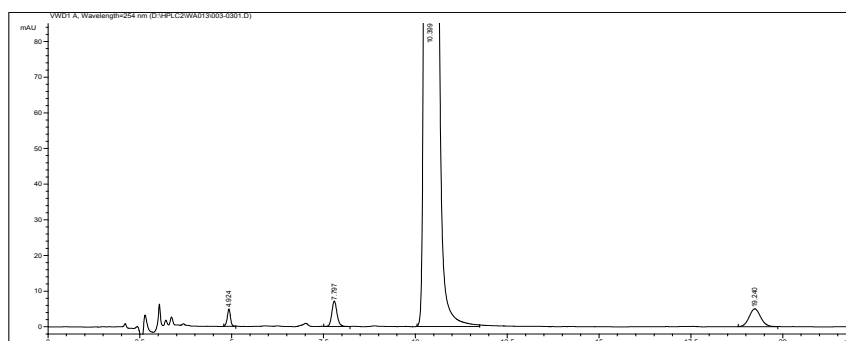
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: citric acid (dissolve 3 g of citric acid in 900 mL of water); acetonitrile = 86:14
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA013001-0101



The chromatogram of the test solution--- HPLC2WA013002-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ceftezole	10.41	25533.9	12573	9.0	1.05
Impurity1	4.92	29.8	17124		0.96
Impurity2	7.80	69.5	15887	14.4	1.12
Impurity3	19.24	110.7	18287	19.6	1.08

# Cefazolin Sodium – 头孢唑林钠

## Cefazolin Sodium (0421-9603) – Method number WR013

### Assay

Test solution: Accurately weigh about 50mg of the substance in a 20 mL volumetric flask, dissolve in mobile phase, dilute to volume, mix well and use as the test solution.

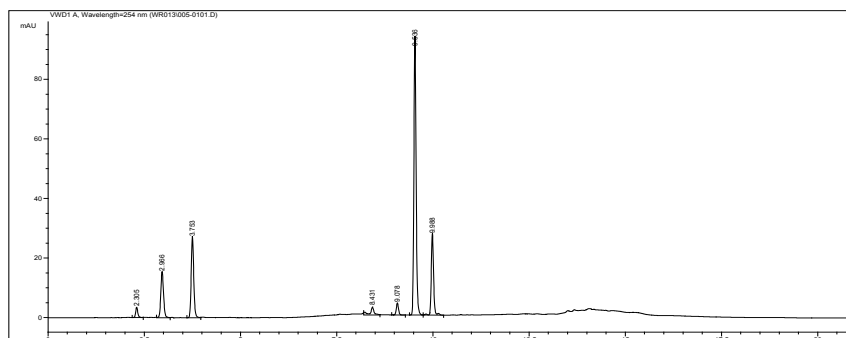
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the reference solution. Dissolve about 10 mg in 10 mL of 0.2 % sodium hydroxide solution. Allow to stand for 15-30 minutes. Accurately measure 1 mL of the solution and dilute to 20 mL with mobile phase. Mix well and use for system suitability test.

### Chromatographic conditions

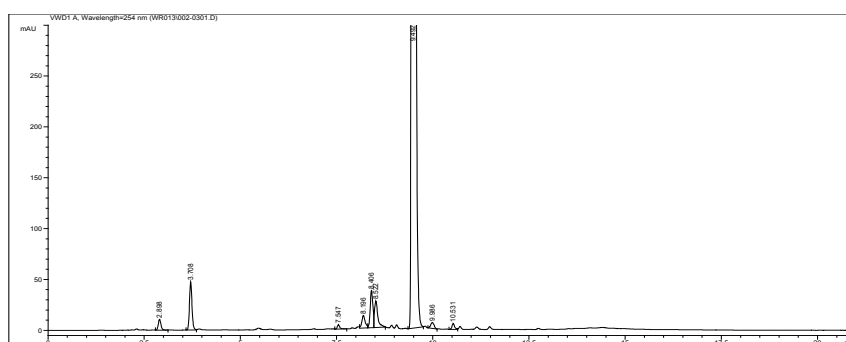
- Column: Agilent ZORBAX SB-Aq 4.6×50mm, 5 µm (880975-902)
- Mobile phase: A: 1.454 % disodium hydrogen phosphate and 0.353 % potassium dihydrogen phosphate B: acetonitrile
- Gradient: 0 min, 98 %A; 2 min, 98 %A; 4 min, 90 %A; 10 min, 70 %A; 11.5 min, 50 %A; 12 min, 50 %A; 15 min, 98 %A; 21 min, 98 %A
- Flow rate: 1.2 mL/ min
- Injection volume: 10 µL
- Column temperature: 45 °C
- Detector wavelength: 254 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability---HPLC2\WR013\005-0101.D



The chromatogram of the test solution--- HPLC2\WR013\002-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefazolin Sodium	9.53	379.1	139022	4.4	1.15
Degradation product1	2.30	13.8	9089	/	1.20
Degradation product2	2.96	77.7	8713	5.9	1.12
Degradation product3	3.75	124.3	16886	6.5	1.13
Degradation product4	9.99	110.1	150117	4.4	1.12

# Sultamicillin Tosilate Capsules – 托西酸舒他西林胶囊

Sultamicillin (130491-200102), Ampicillin (0410-200004),

Sulbactam (130430-200305) – Method number WA258

## Assay

Test solution: Dissolve an accurately weighed quantity of the well-mixed contents in mobile phase, dilute to volume, mix well, filter and use the filtrate as the test solution containing 0.2 mg of sultamicillin per mL.

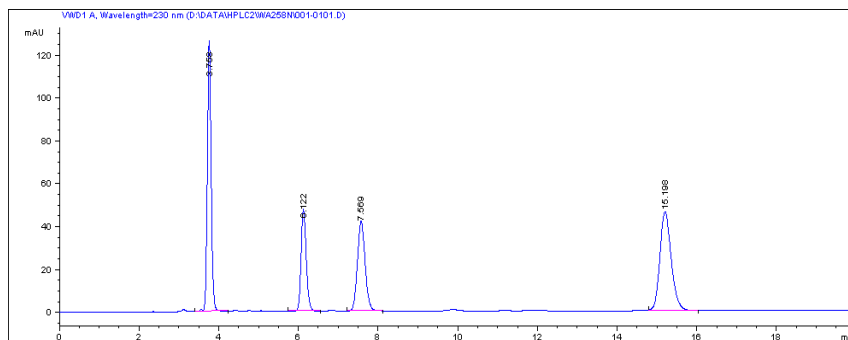
Reference solution: Repeat the procedure using Sultamicillin CRS to produce the reference solution. Dissolve a quantity of sultamicillin CRS, ampicillin CRS, sulbactam CRS to produce a mixture of 0.2 mg of each component per ml for the system suitability test.

## Chromatographic conditions

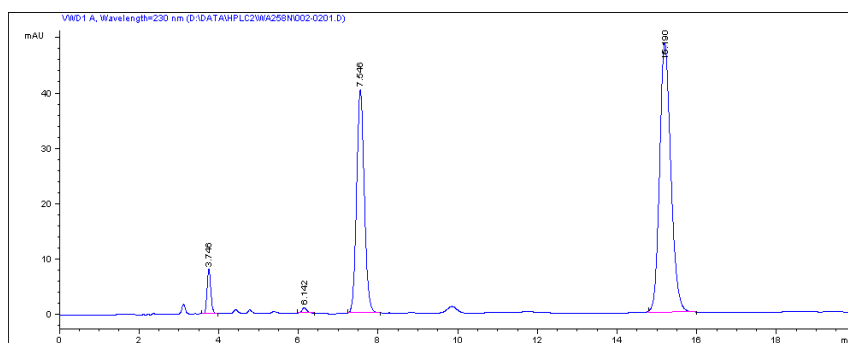
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: tetradecylam minimum hydroxide solution (to 80 mL of 10 % tetradecylam minimum hydroxide solution add 900 mL of water and 4 mL of triethylamine, adjust pH to 4.0 with phosphoric acid and dilute to 1000 mL with water):methanol = 60:40
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC2\WA258N\004-0301



The chromatogram of the test solution --- HPLC2\WA258N\006-0501

Constituents (Test solution)	Ret Time ( min)	Area (mAU*s)	N	Rs	USP T <sub>i</sub>
Ampicillin	3.75	53.1	7664	/	1.12
Sulbactam	6.14	9.0	10795	11.7	1.04
Sultamicillin	7.55	541.4	7776	4.8	1.09
Tosilic acid	15.19	951.2	14585	11.2	1.16

# Tretinoin Cream – 维A酸乳膏

Tretinoin (100307-200201) – Method number WA189

## Assay

Test solution: Accurately weigh a quantity of the cream, equivalent to about 1 mg of tretinoin, in a small beaker, add 15 mL of isopropanol and shake well. Transfer with separate portions of methanol to a 100 mL volumetric flask, treat ultrasonically for 10 minutes, allow to cool to room temperature, dilute with methanol to volume, shake well, filter and use the filtrate as the test solution.

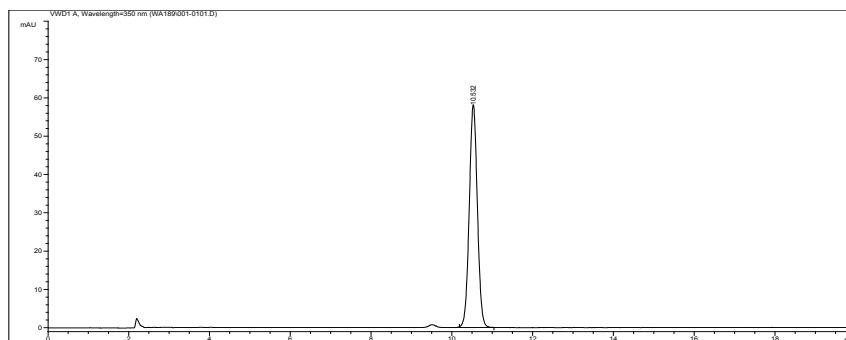
Reference solution: Accurately weigh about 10 mg of tretinoin CRS in a 100 mL volumetric flask, dissolve in 10 mL isopropanol, dilute with methanol to volume and mix well. Accurately measure 5 mL of the solution in a 50 mL volumetric flask, dilute with methanol to volume, mix well and use as the reference solution.

## Chromatographic conditions

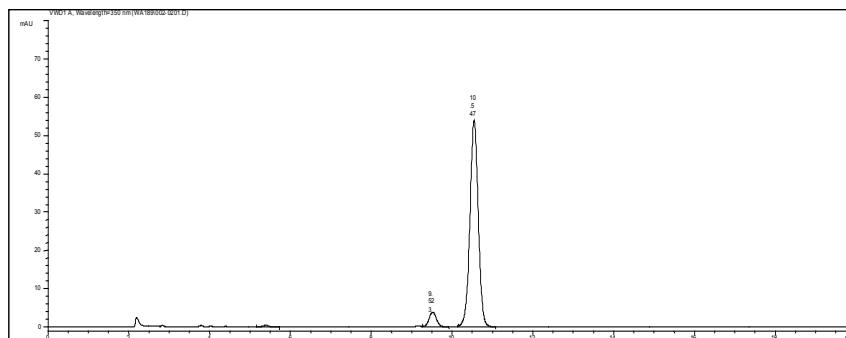
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : 0.2 % glacial acetic acid = 90:10
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 350 nm

## Chromatographic system HPLC

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA189\001-0101



The chromatogram of the test solution --- HPLC1\WA189\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Iso-Tretinoin	9.52	48.8	13670	/	1.03
Tretinoin	10.55	774.5	13211	2.95	1.00

# Vitamin B6 – 维生素B6

Pyridoxine hydrochloride (0116-9801) – Method number WA190

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase to produce the test solution containing 1.0 mg/mL.

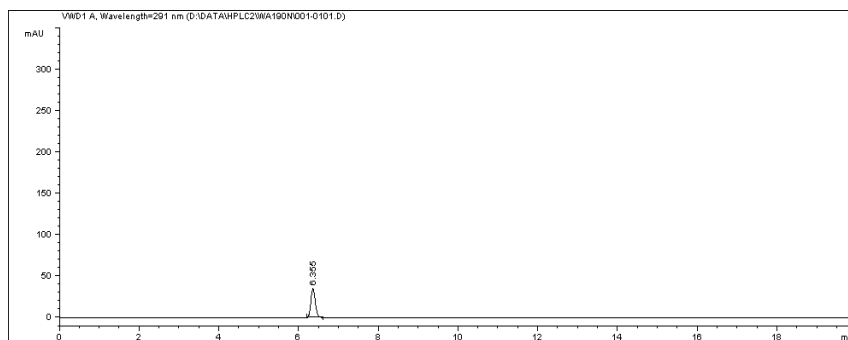
Reference solution: Dissolve a quantity of the substance in mobile phase to produce the reference solution containing 10 µg/mL.

## Chromatographic conditions

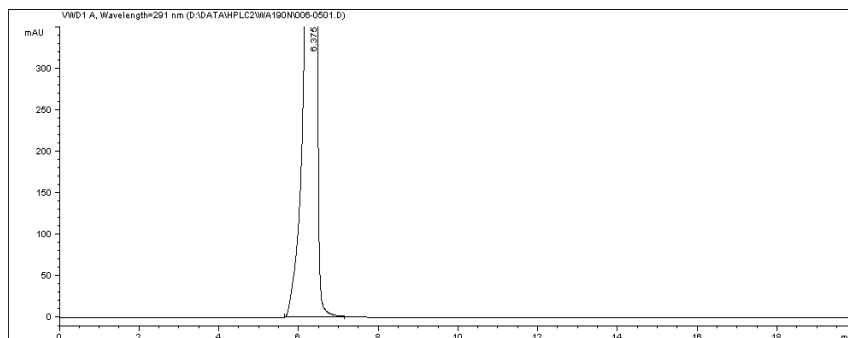
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: 0.02 % sodium pentylsulfonate ( adjust pH to 3.0 with glacial acetic acid) = 15:85
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 291 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA190\N001-0101



The chromatogram of the test solution --- HPLC1\WA190\N008-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Vitamin B6	6.37	26614.8	5955	/	/

# Vitamin B6 Tablets – 维生素B6片

Pyridoxine Hydrochloride (0116-9801) – Method number WA191

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 100 mg of vitamin B6, in a 100 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolve the vitamin B6, dilute to volume with mobile phase, mix well and filter. Accurately measure 5 mL of the filtrate in 50 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the test solution.

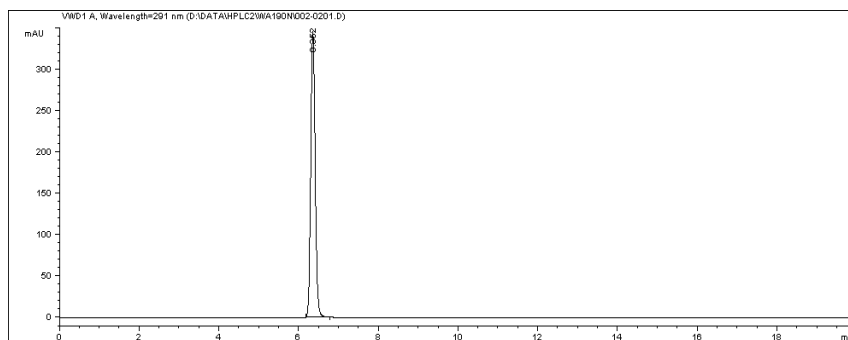
Reference solution: Repeat the procedure using pyridoxine hydrochloride CRS to produce the reference solution.

## Chromatographic conditions

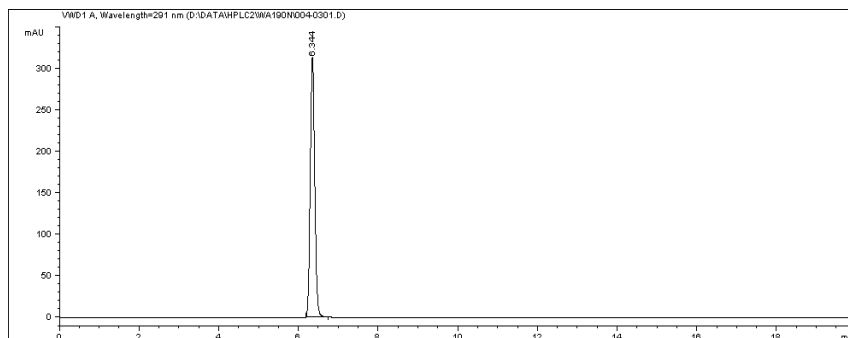
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:0.02 %sodium pentylsulfonate (adjust pH to 3.0 with glacial acetic acid) = 15:85
- Flow rate: 1.0 mL/ min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 291 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA190N\002-0201



The chromatogram of the test solution --- HPLC2\WA190N\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vitamin B6	6.34	2454.9	15987	/	1.09

# Vitamin B6 Tablets – 维生素B6片

Pyridoxine Hydrochloride (0116-9801) – Method number WA191

## Assay

Test solution: Dissolve a quantity of the powder in mobile phase to produce a solution of 1.0 mg vitamin B6 per mL, filter and use the filtrate as the test solution.

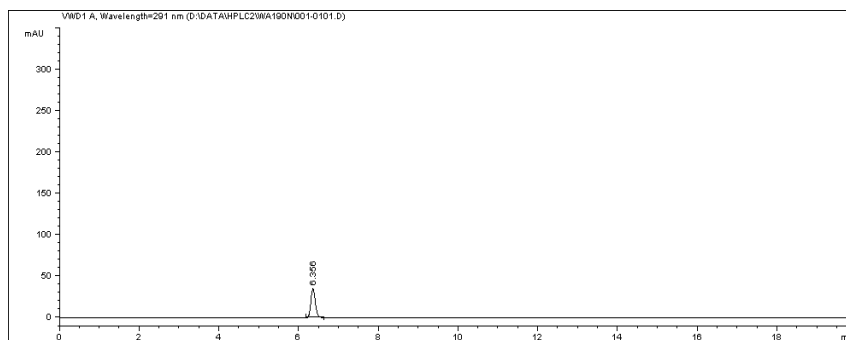
Reference solution: Dilute a quantity of the test solution with mobile phase to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

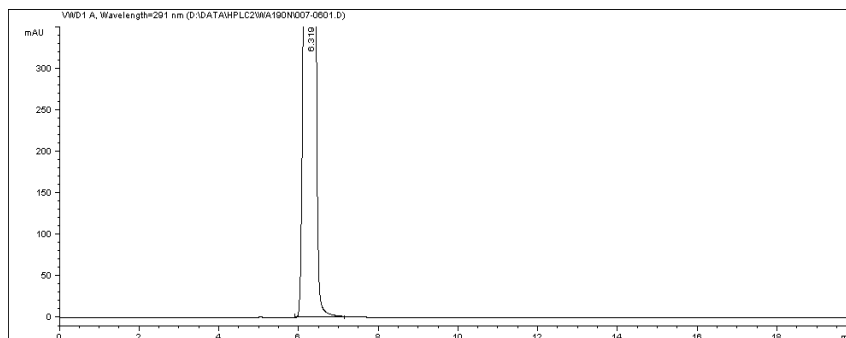
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: 0.02 % sodium pentylsulfonate (adjust pH to 3.0 with glacial acetic acid) = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 291 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA190N001-0101



The chromatogram of the test solution--- HPLC2WA190N007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vitamin B6	6.32	24270.8	4439	/	0.81

# Vitamin B6 Injection – 维生素B6注射液

Vitamin B6 (0116-9801) – Method number WA192

## Assay

Test solution: Accurately measure a quantity of the injection fluid and dilute with mobile phase to produce the test solution of 0.1 mg of vitamin B6 per mL.

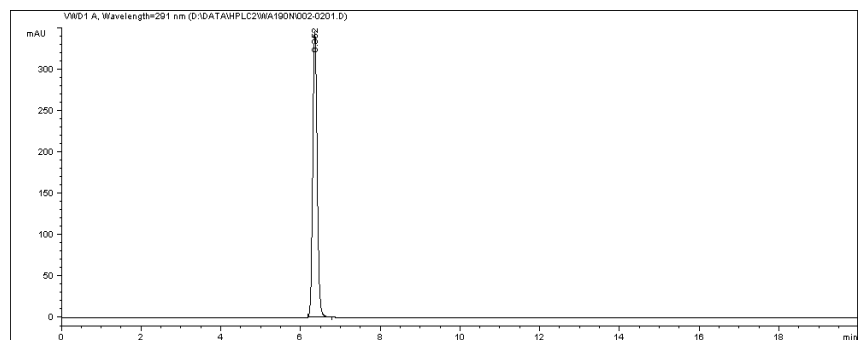
Reference solution: Repeat the procedure using vitamin B6 to produce the reference solution.

## Chromatographic conditions

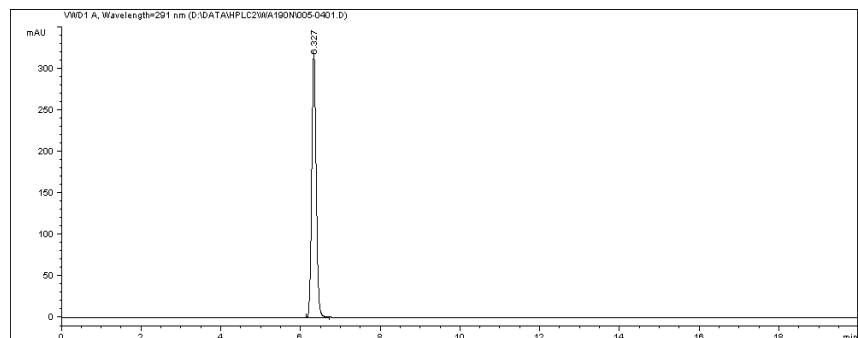
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: 0.02 % sodium pentylsulfonate (adjust pH to 3.0 with glacial acetic acid) = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 291 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA190N002-0201



The chromatogram of the test solution --- HPLC2WA190N005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vitamin B6	6.33	2492.8	15475	/	1.08



# Vitamin B6 Injection – 维生素B6注射液

Pyridoxine Hydrochloride (0116-9801) – Method number WA192

## Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce the test solution containing 1.0 mg of vitamin B6 per mL.

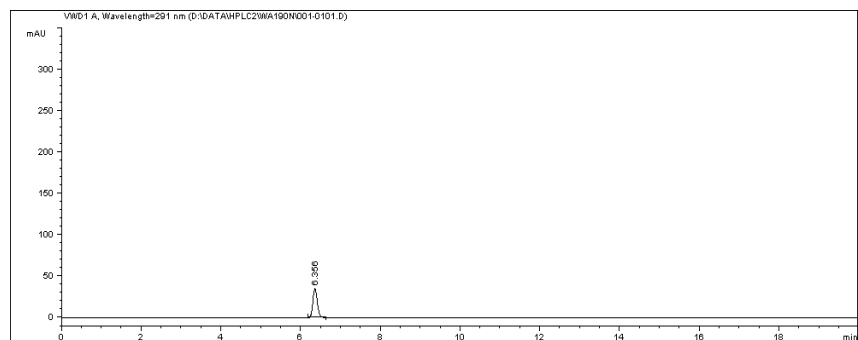
Reference solution: Dilute a quantity of the injection fluid with mobile phase to produce the reference solution containing 10 µg/mL.

## Chromatographic conditions

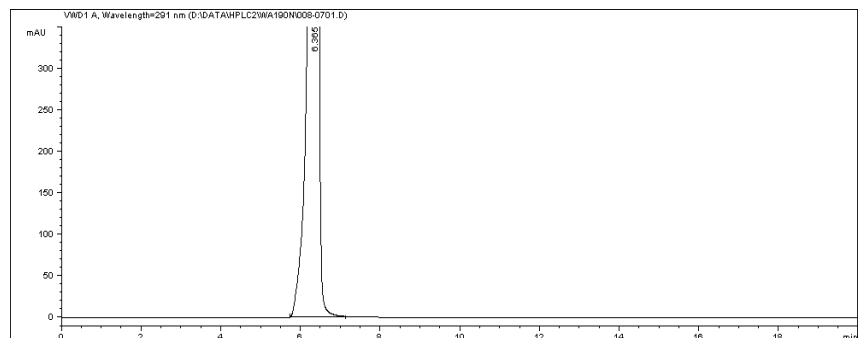
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: 0.02 % sodium pentylsulfonate (adjust pH to 3.0 with glacial acetic acid) = 15:85
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 291 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA190N001-0101



The chromatogram of the test solution --- HPLC2WA190N008-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vitamin B6	6.37	24284.6	6776	/	/

# Ubenimex – 乌苯美司

Ubenimex (100371-200302) – Method number WA332

## Assay

Test solution: Dissolve a quantity in 30 % acetic acid to produce the test solution of 10 mg/mL.

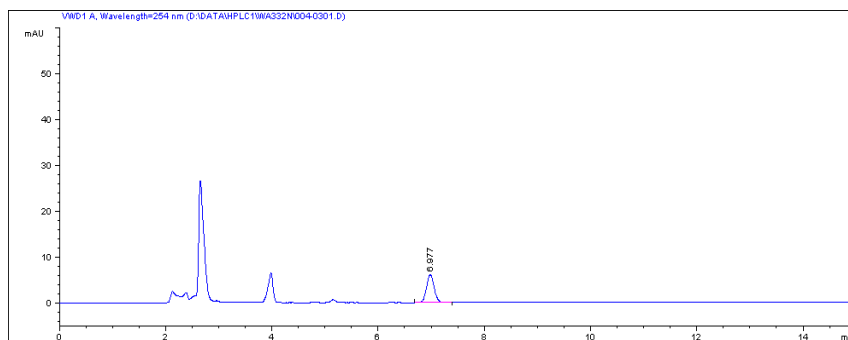
Reference solution: Dissolve a quantity in 30 % acetic acid to produce the reference solution of 0.1 mg/mL.

## Chromatographic conditions

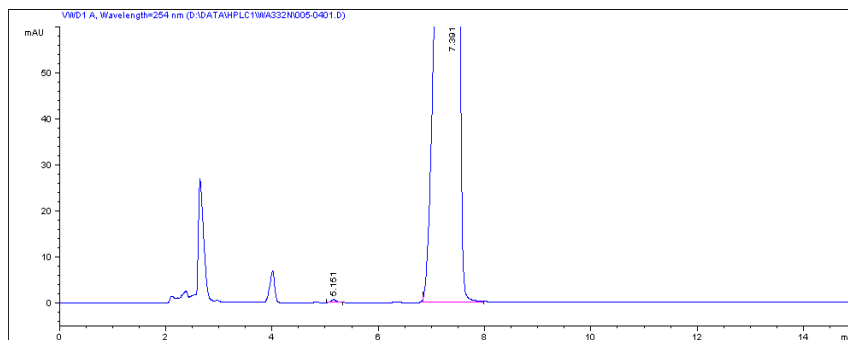
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: 0.6 % sodium dihydrogen phosphate = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 40 °C
- Detector wavelength: 254nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA332N004-0301



The chromatogram of the test solution--- HPLC1\WA332N005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ubenimex	7.39	5815.0	2660	6.0	0.70
Impurity	5.15	4.5	14495	/	/

# Ubenimex Capsules – 乌苯美司胶囊

## Ubenimex (100371-200302) – Method number WA240

### Assay

**Test solution:** Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of ubenimex, in a 50 mL volumetric flask, add a quantity of 17 % acetic acid solution, shake thoroughly to dissolve the ubenimex, dilute with 17 % acetic acid solvent to volume, mix well, filter and use the filtrate as test solution.

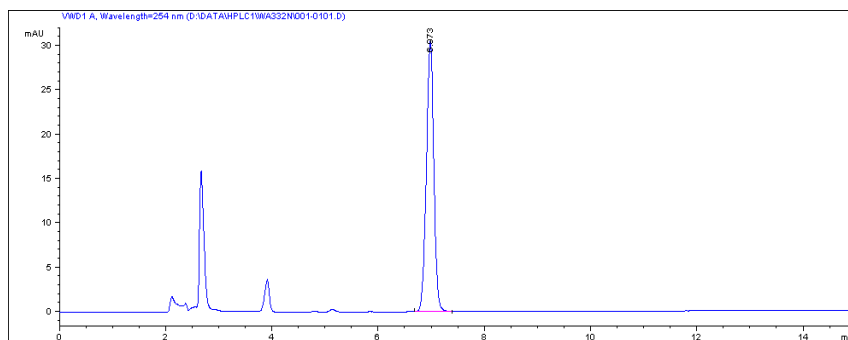
**Reference solution:** Dissolve an accurately weighed quantity of ubenimex CRS in 17 % acetic acid solution to produce the reference solution of 1 mg/mL.

### Chromatographic conditions

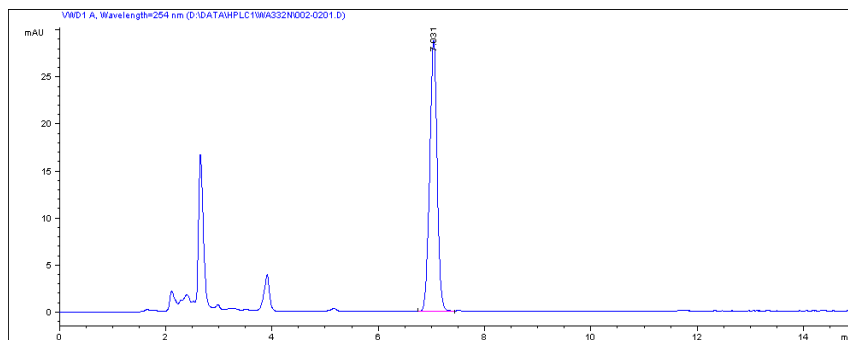
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol: 0.6 % sodium phosphate solution = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 40 °C
- Detector wavelength: 254nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA332N001-0101



The chromatogram of the test solution --- HPLC1WA332N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ubenimex	7.03	281.7	12099	/	0.99

# Raceanisodamine Tablets – 消旋山莨菪碱片

Raceanisodamine (100249-199501) – Method number WA158

## Assay

Test solution: Accurately weigh 20 (10 mg) or 40 (5 mg) tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 10 mg of raceanisodamine, in a 50 mL volumetric flask, add a quantity of mobile phase, shake to dissolve the raceanisodamine. Dilute to volume with mobile phase, mix well, filter and use the filtrate as the test solution.

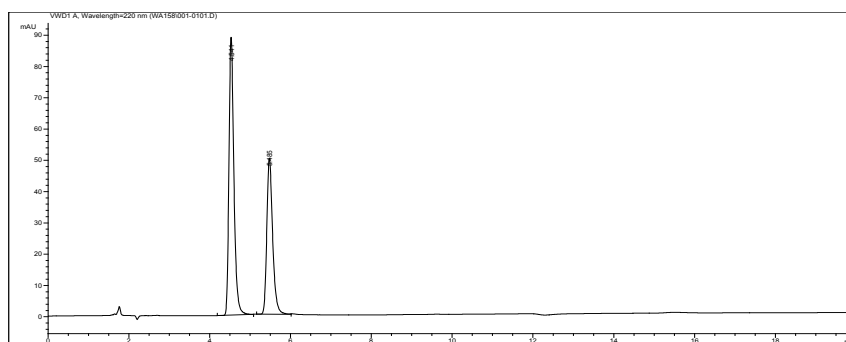
Reference solution: Repeat the procedure using raceanisodamine CRS to produce the reference solution.

## Chromatographic conditions

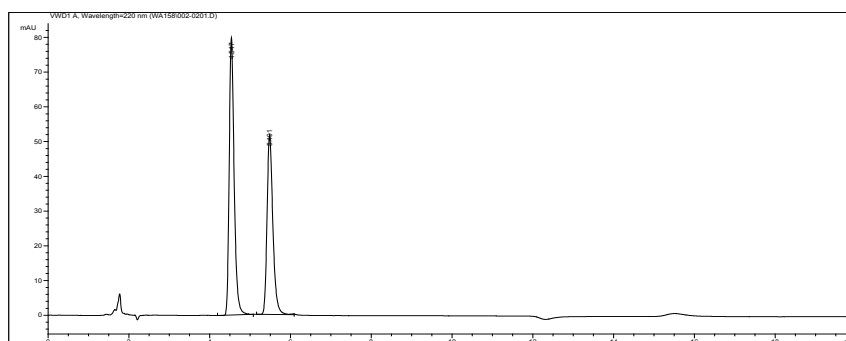
- Column : Agilent ZORBAX Extend-C18 4.6×250 mm, 5 µm (770450-902)
- Mobile phase: 0.02 % triethylamine:methanol = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA158001-0101



The chromatogram of the test solution --- HPLC1WA158002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cis-Raceanisodamine	4.55	683.3	6354	/	1.24
trans-Raceanisodamine	5.49	530.7	7386	3.9	1.24

# Nitroglycerin Aerosol – 硝酸甘油气雾剂

Nitroglycerin (100236-200401) – Method number WA211

## Assay

Test solution: Punch a hole in the aluminum cover of the container and insert an injection needle with dry rubber tubing into the container (do not allow to come in contact with the surface of the liquid). Put the other end of the rubber tubing in a 100 mL volumetric flask containing 50 mL of mobile phase, allow the propellant to expel completely, remove the aluminum cover. Transfer the residual content to the 100 mL volumetric flask. Wash the aluminum cover and the container with mobile phase, add the washings to the same volumetric flask, dilute with mobile phase to volume, mix well, filter and use the filtrate as the test solution.

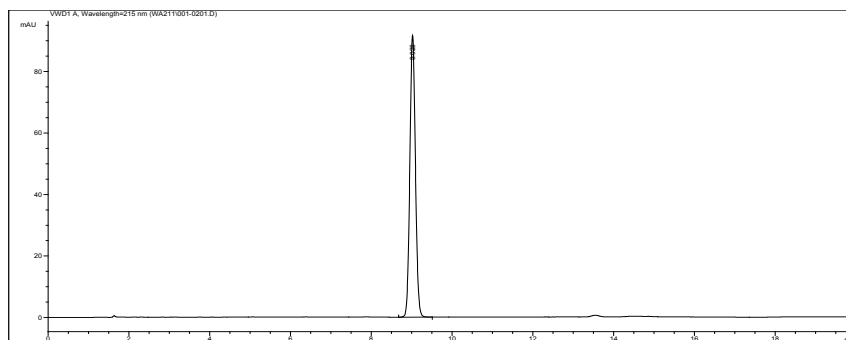
Reference solution: Dilute an accurately weighed quantity of nitroglycerin CRS with mobile phase to produce the reference solution of 0.1 mg/mL.

## Chromatographic conditions

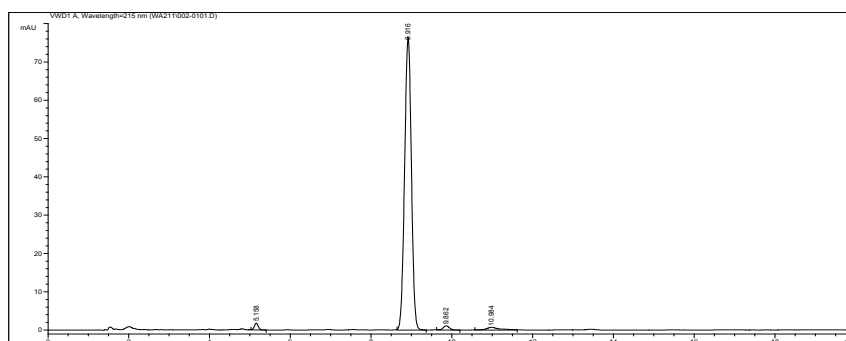
- Column: ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: acetonitrile:water = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 215 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA211\001-0201



The chromatogram of the test solution ---HPLC1\WA211\002-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nitroglycerin	8.92	890.7	13416	/	1.00

# Miconazole Nitrate Liniment – 硝酸咪康唑搽剂

Miconazole Nitrate (10213-9903) – Method number WA212

## Assay

Test solution: Accurately measure 2 mL of the liniment, equivalent to 40 mg of miconazole nitrate, in a 100 mL volumetric flask, dilute to volume with methanol, mix well and use as the test solution.

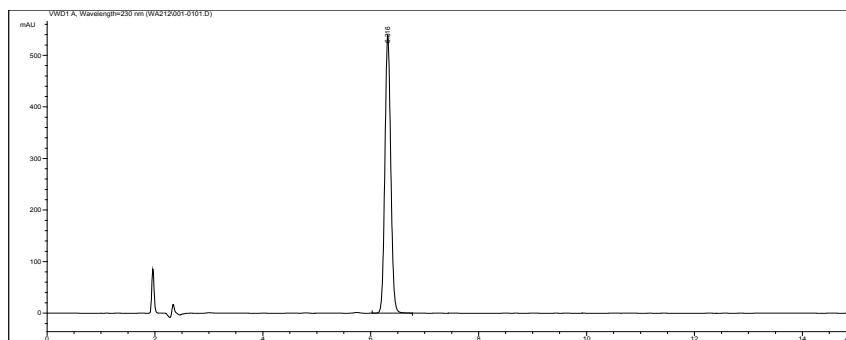
Reference solution: Accurately weigh about 20 mg of miconazole nitrate CRS in a 50 mL volumetric flask, dissolve in methanol, dilute to volume, mix well and use as the reference solution.

## Chromatographic conditions

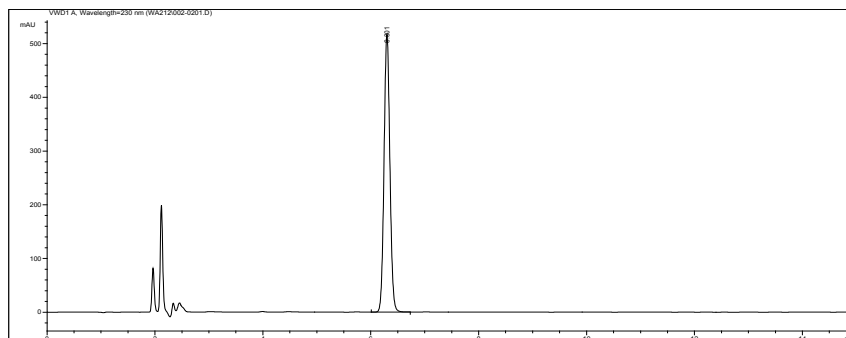
- Column: Agilent ZORBAX SB-C18 4.6×150 mm, 5 µm (880975-902)
- Mobile phase: 0.5 % ammonium acetate solution: acetonitrile: methanol = 10:45:45
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1WA212001-0101



The chromatogram of the test solution --- HPLC1WA200006-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Miconazole Nitrate	6.30	3898.4	15772	/	1.054

# Calcium Folate – 亚叶酸钙

## Calcium Folate – Method number WR154

### Assay

Test solution: Dissolve a quantity in water to produce the test solution containing 1 mg/mL.

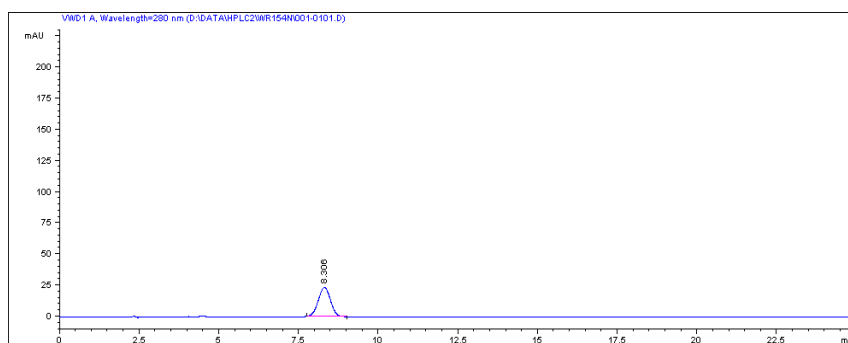
Reference solution: Dissolve a quantity in water to produce the reference solution containing 10 µg/mL.

### Chromatographic conditions

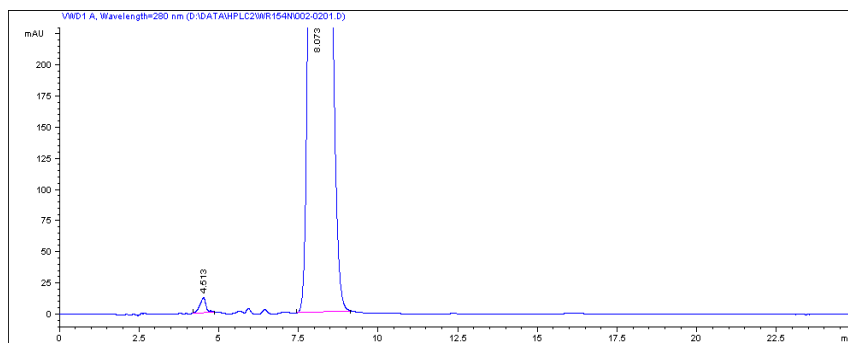
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : sodium dihydrogen phosphate BS containing 0.1 % tetrabutylammonium hydroxide solution (dissolve 2.0 mL of 40 % tetrabutylammonium hydroxide solution and 2.2g of disodium hydrogen phosphate in water to 780 mL, adjust pH to 7.8 with phosphoric acid) = 22:78
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 40 °C
- Detector wavelength: 280 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR154N001-0101



The chromatogram of the test solution --- HPLC2\WR154N 002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity	4.51	171.3	2921	/	1.15
Calcium Folate	8.07	59972.3	2000	6.7	1.35

# Calcium Folate Tablets – 亚叶酸钙片

Calcium Folate – Method number WR027

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in water to produce a solution of 0.1 mg/mL. Filter and use the filtrate as the test solution.

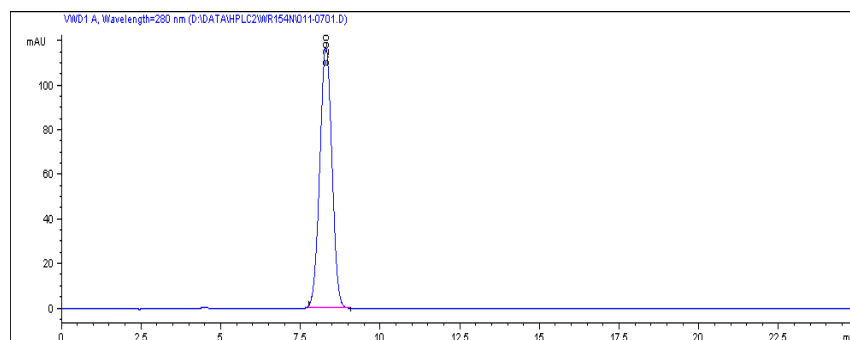
Reference solution: Repeat the procedure using calcium foliate CRS to produce the reference solution.

## Chromatographic conditions

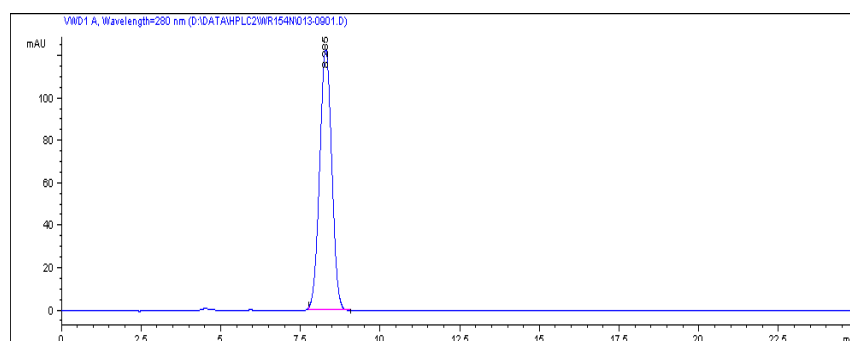
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol-sodium dihydrogen phosphate BS containing 0.1 % tetrabutylammonium hydroxide (to 2.0 mL of 40 % tetrabutylammonium and 2.2 g of disodium hydrogen phosphate, add water to 780 mL, adjust pH to 7.8 with phosphoric acid) =22:78
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 40 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR154N\011-0701



The chromatogram of the test solution --- HPLC2\WR154N\013-0901

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Calcium Folate	8.29	3261.8	2288	/	1.00



# Calcium Folate Tablets – 亚叶酸钙片

## Calcium Folate – Method number WR027

### Assay

Test solution: Accurately weigh a quantity of the finely powdered tablets and dissolve in water to produce a solution of 1 mg/mL, filter and use the filtrate as the test solution.

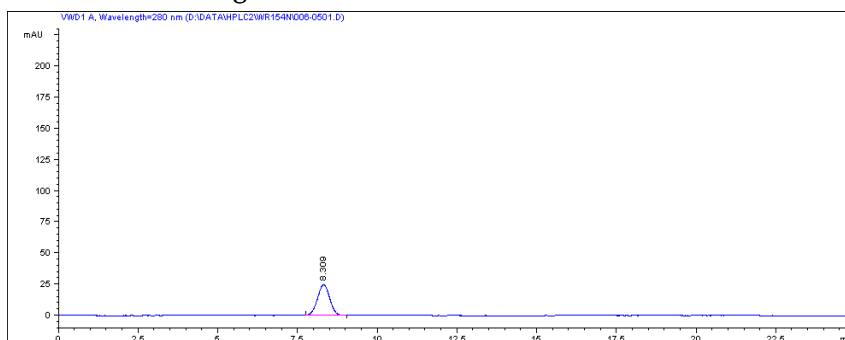
Reference solution: Dilute an accurately measured quantity of the test solution with water to produce the reference solution of 10 µg/mL.

### Chromatographic conditions

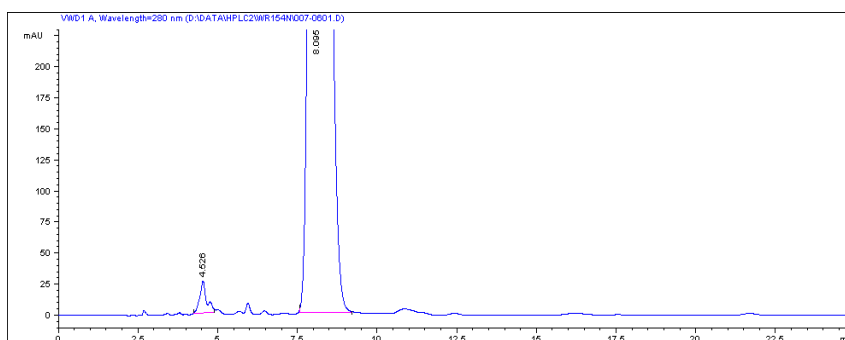
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol-sodium dihydrogen phosphate BS containing 0.1 % tetrabutylammonium hydroxide (to 2.0 mL of 40 % tetrabutylammonium and 2.2 g of disodium hydrogen phosphate, add water to 780 mL, adjust pH to 7.8 with phosphoric acid) = 22:78
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 40 °C
- Detector wavelength: 280 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR154N006-0501



The chromatogram of the test solution--- HPLC2\WR154N\007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity	4.53	396.8	3426	/	/
Calcium Folate	8.09	66274.7	1861	6.7	1.35

# Ambroxol Hydrochloride – 盐酸氨溴索

Ambroxol Hydrochloride (100599-200301) – Method number WA176

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase to produce the test solution containing 1 mg/mL.

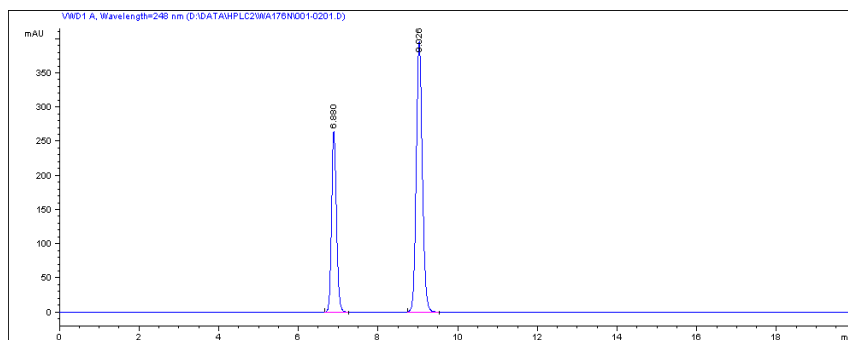
Reference solution: Dissolve a quantity of the substance in mobile phase to produce the reference solution containing 10 µg/mL. Dissolve 5 mg in 0.2 mL of methanol, add 40 µL of 1 % formaldehyde solution, mix well, heat at 60 °C for 5 minutes, dry under nitrogen, dissolve the residue in 5 mL of water, dilute with mobile phase to 20 mL and use for the system suitability test.

## Chromatographic conditions

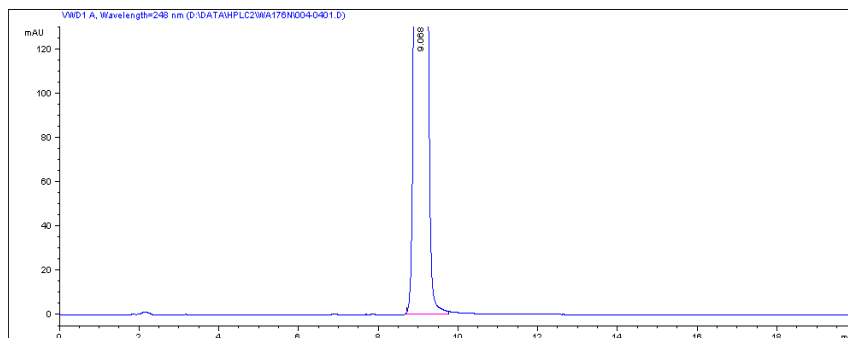
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: 0.01 mol/L ammonium dihydrogenphosphate solution (adjust pH to 7.0 with phosphate acid) = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability---HPLC2\WA176N001-0201



The chromatogram of the test solution--- HPLC2\WA176N004-0401

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ambroxol Hydrochloride	9.02	4237.4	16090	8.4	1.08
Impurity B	6.89	2263.4	15296	/	1.10

# Ambroxol Hydrochloride Sustained Release Capsules

Ambroxol Hydrochloride (100599-200301) – Method number WA181

盐酸氨溴索缓释胶囊

## Assay

Test solution: Accurately weigh a quantity of the contents of the capsules and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase to produce the test solution of 30 µg/mL.

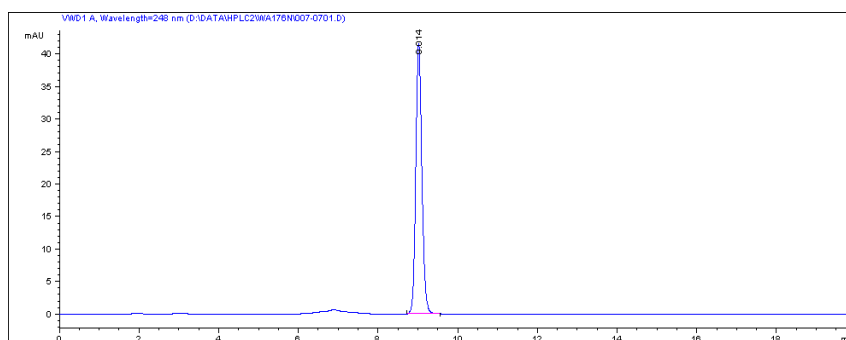
Reference solution: Repeat the procedure using ambroxol hydrochloride CRS to produce the reference solution of 30 µg/mL.

## Chromatographic conditions

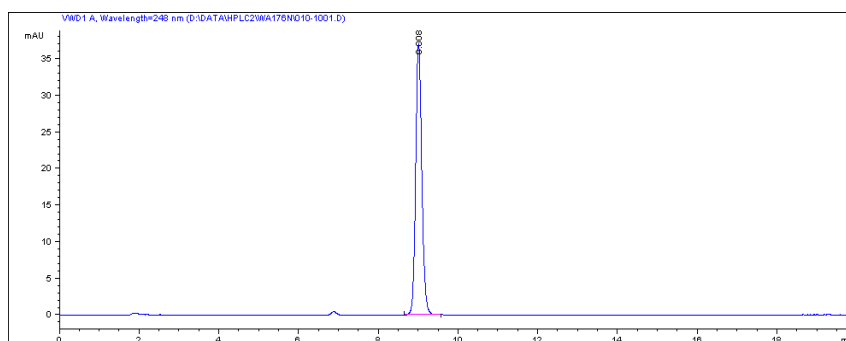
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: 0.01 mol/L ammonium dihydrogen phosphate solution (adjust pH to 7.0 with phosphate acid) = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA176N007-0701



The chromatogram of the test solution--- HPLC2WA176N010-1001

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ambroxol Hydrochloride	9.01	397.4	16508	/	1.10

# Ambroxol Hydrochloride Sustained Release Capsules

Ambroxol Hydrochloride (100599-200301) – Method number WA181  
盐酸氨溴索缓释胶囊

## Assay

Test solution: Dissolve a quantity of the powder in mobile phase to produce the test solution containing 1 mg/mL.

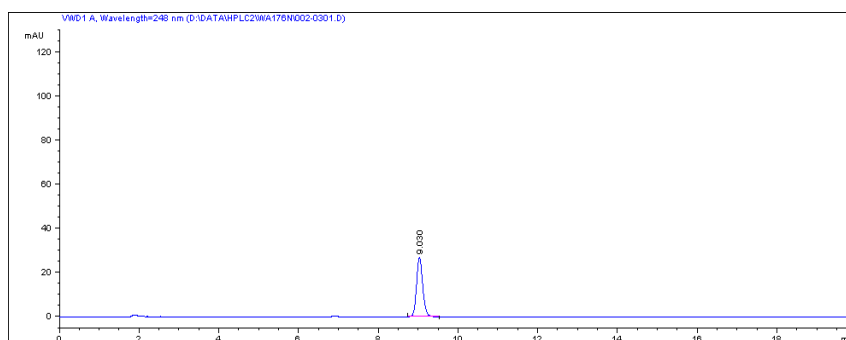
Reference solution: Dissolve a quantity of the powder in mobile phase to produce the reference solution containing 10 µg/mL.

## Chromatographic conditions

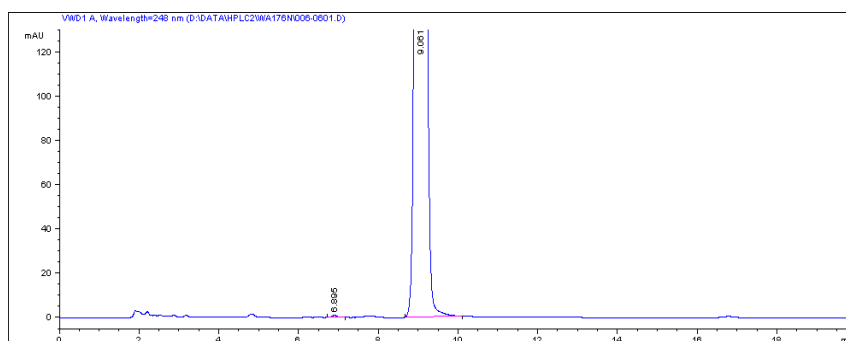
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: 0.01 mol/L ammonium dihydrogen phosphate solution (adjust pH to 7.0 with phosphate acid) = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA176N002-0301



The chromatogram of the test solution--- HPLC2WA176N006-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ambroxol Hydrochloride	9.06	22833.0	14897	8.3	0.99
Impurity B	6.89	7.8	14964	/	/

# Ambroxol Hydrochloride Oral Solution – 盐酸氨溴索口服溶液

## Ambroxol Hydrochloride (100599-200301) – Method number WA177

### Assay

Test solution: Accurately measure a quantity in mobile phase to produce the test solution of 30 µg/mL.

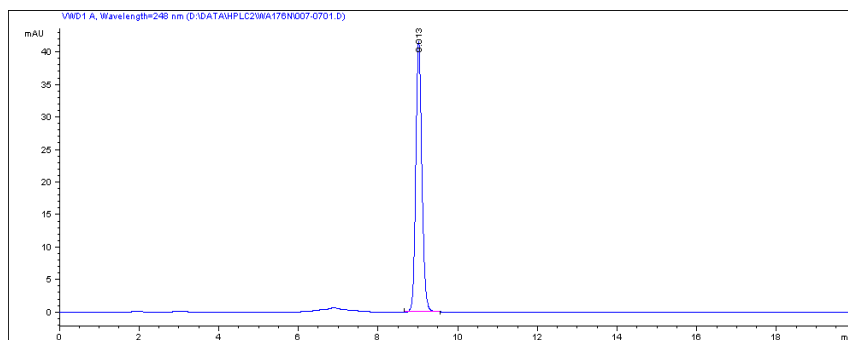
Reference solution: Repeat the procedure using ambroxol hydrochloride CRS to produce the reference solution, in which the concentration is equivalent to the test solution.

### Chromatographic conditions

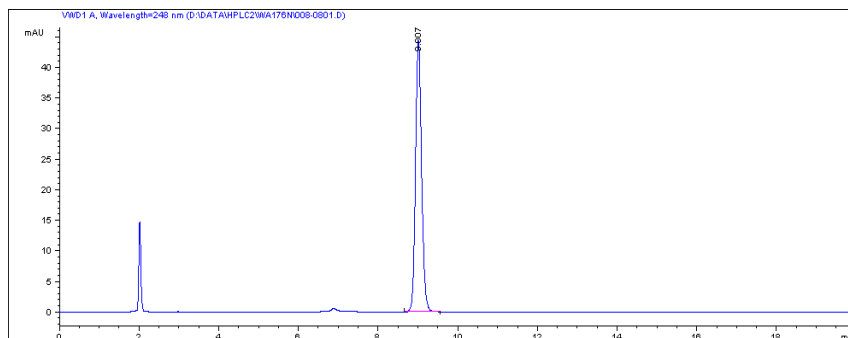
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: 0.01 mol/L ammonium dihydrogenphosphate solution (adjust pH to 7.0 with phosphate acid) = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA176N007-0701



The chromatogram of the test solution--- HPLC2WA176N008-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ambroxol Hydrochloride	9.01	472.5	13939	/	1.09

# Ambroxol Hydrochloride Tablets – 盐酸氨溴索片

Ambroxol Hydrochloride (100599-200301) – Method number WA178

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase to produce the test solution of 30 µg/mL.

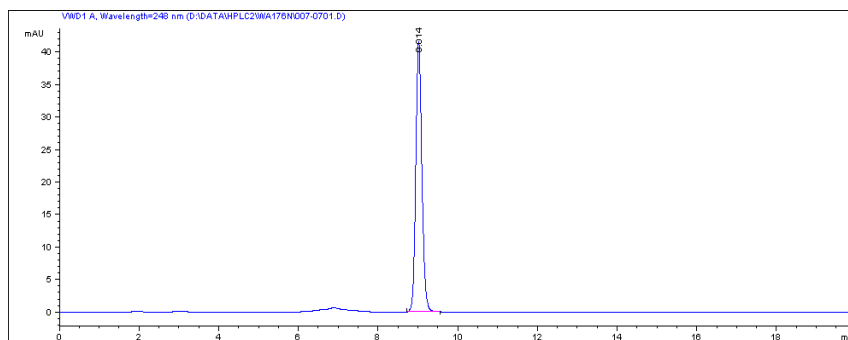
Reference solution: Repeat the procedure using ambroxol hydrochloride CRS to produce the reference solution, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

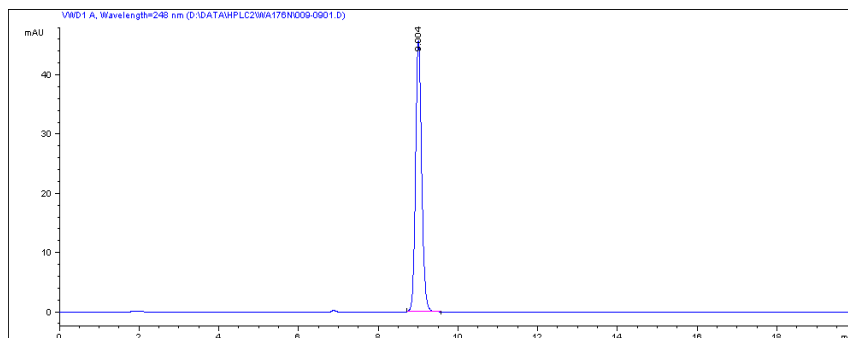
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: 0.01 mol/L ammonium dihydrogenphosphate solution (adjust pH to 7.0 with phosphate acid) = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA176N007-0701



The chromatogram of the test solution--- HPLC2WA176N009-0901

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ambroxol Hydrochloride	9.00	490.6	16992	/	1.10

# Ambroxol Hydrochloride Tablets – 盐酸氨溴索片

Ambroxol Hydrochloride (100599-200301) – Method number WA178

## Assay

Test solution: Dissolve a quantity of powdered tablets in the mobile phase to produce the test solution containing 1 mg/mL.

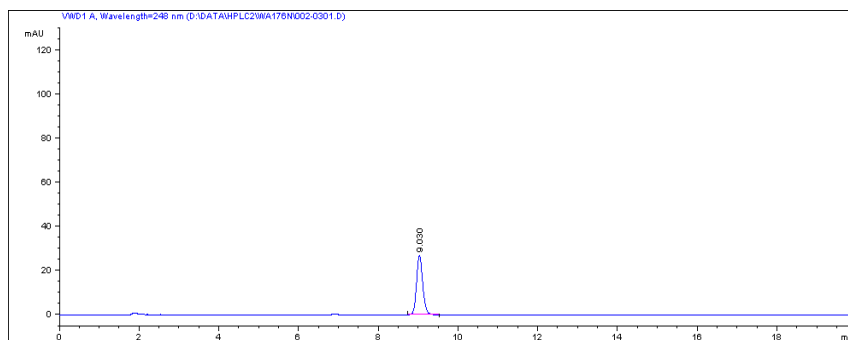
Reference solution: Dissolve a quantity of powdered tablets in the mobile phase to produce the reference solution containing 10 µg/mL.

## Chromatographic conditions

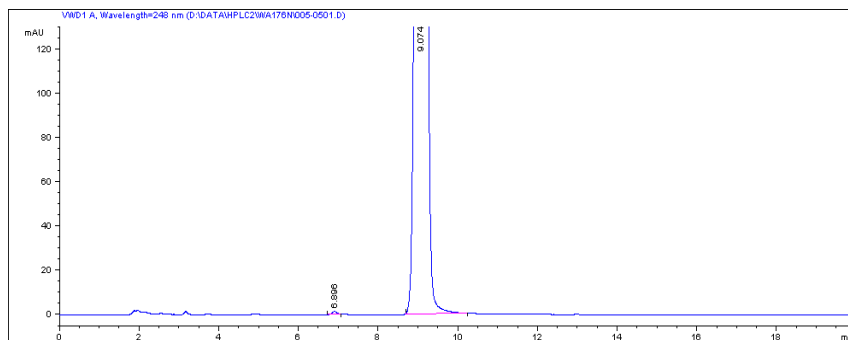
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: acetonitrile: 0.01 mol/L ammonium dihydrogen phosphate solution (adjust pH to 7.0 with phosphate acid) = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 248 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA176N002-0301



The chromatogram of the test solution--- HPLC2WA176N005-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ambroxol Hydrochloride	9.07	30301.8	14944	8.3	0.96
Impurity B	6.90	13.0	14971	/	1.10

# Ondansetron Hydrochloride – 盐酸昂丹司琼

Ondansetron hydrochloride (100559-200301) – Method number WA168

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution of 0.5 mg/mL.

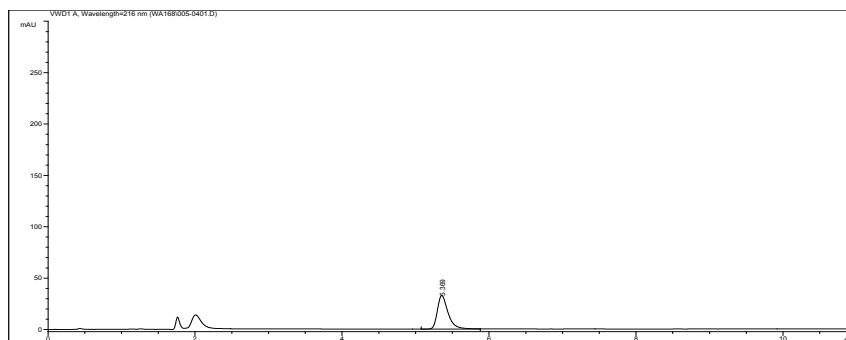
Reference solution: Accurately measure a quantity of the test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

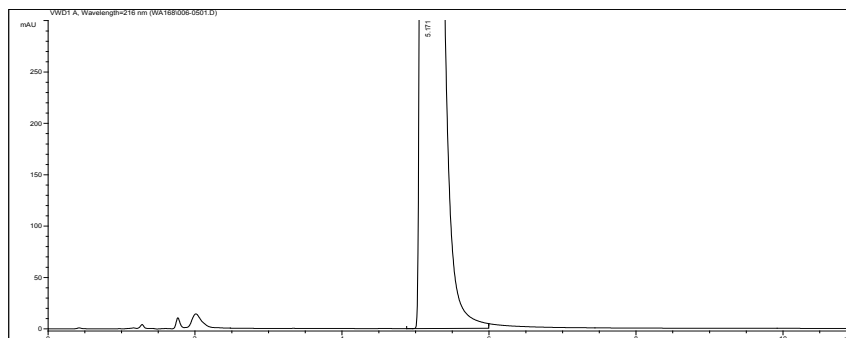
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.02M sodium dihydrogen phosphate (pH 5.4): acetonitrile = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 216 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA168\005-0401



The chromatogram of the test solution--- HPLC1\WA168\006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ondansetron Hydrochloride	5.17	31266.1	3248	/	1.65



# Ondansetron Hydrochloride Tablets

Ondansetron hydrochloride (100559-200301) – Method number WA169

## Assay

**Test solution:** Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 8 mg of ondansetron, dissolve in mobile phase to produce a solution of 0.1 mg/mL, mix well, filter and use the filtrate as the test solution.

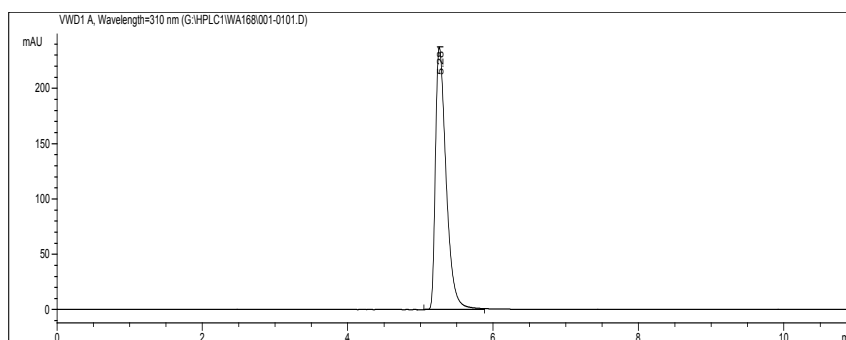
**Reference solution:** Dissolve an accurately weighed quantity of ondansetron hydrochloride CRS with mobile phase to produce a solution of 0.1 mg/mL, mix well and use as the reference solution.

## Chromatographic conditions

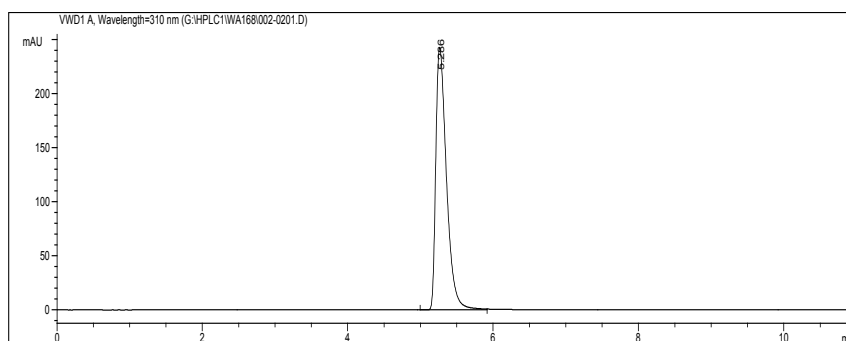
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.02 M sodium dihydrogen phosphate (pH 5.4): acetonitrile = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 216 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1WA168001-0101



The chromatogram of the test solution--- HPLC1WA168002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ondansetron Hydrochloride	5.29	2466.9	5798	/	1.43

# Ondansetron Hydrochloride Tablets – 盐酸昂丹司琼片

Ondansetron hydrochloride (100559-200301) – Method number WA169

## Assay

Test solution: Accurately weigh a quantity of the powdered tablets, equivalent to about 4 mg of ondansetron, in a 10 mL volumetric flask, dissolve the ondansetron hydrochloride in mobile phase, dilute with mobile phase to volume, filter and use the filtrate as the test solution.

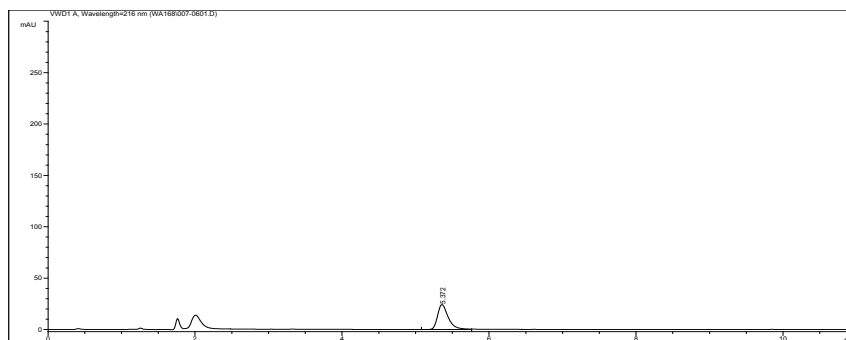
Reference solution: Dilute a quantity of the test solution with mobile phase to produce reference solution of 4 µg/mL.

## Chromatographic conditions

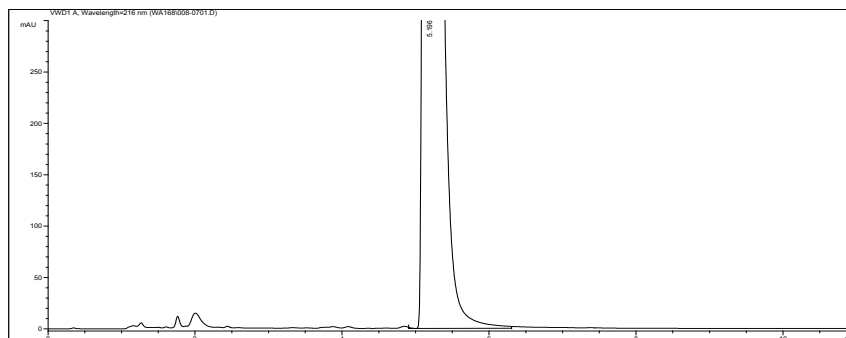
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.02 M sodium dihydrogen phosphate (pH 5.4): acetonitrile = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 216 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA168\007-0601



The chromatogram of the test solution--- HPLC1\WA168\008-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ondansetron Hydrochloride	5.20	25091.2	4174	/	1.59

# Ondansetron Hydrochloride Injection – 盐酸昂丹司琼注射液

Ondansetron hydrochloride (100559-200301) – Method number WA170

## Assay

Test solution: Dilute a quantity of the injection fluid with mobile phase to produce the test solution of 0.1 mg of ondansetron per mL.

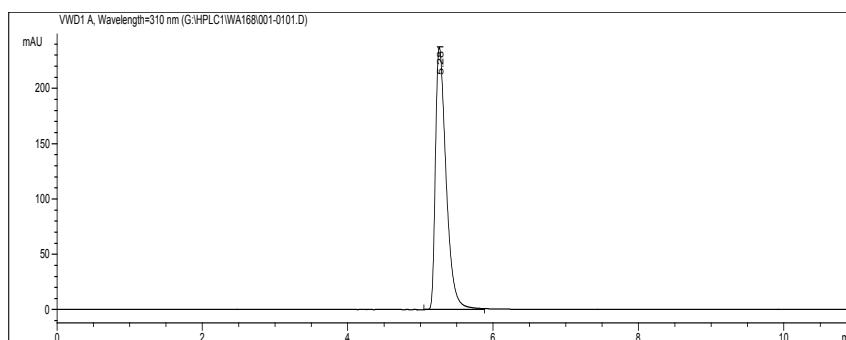
Reference solution: Dissolve an accurately weighed quantity of ondansetron hydrochloride CRS with mobile phase and mix well to produce the reference solution of 0.1 mg/mL.

## Chromatographic conditions

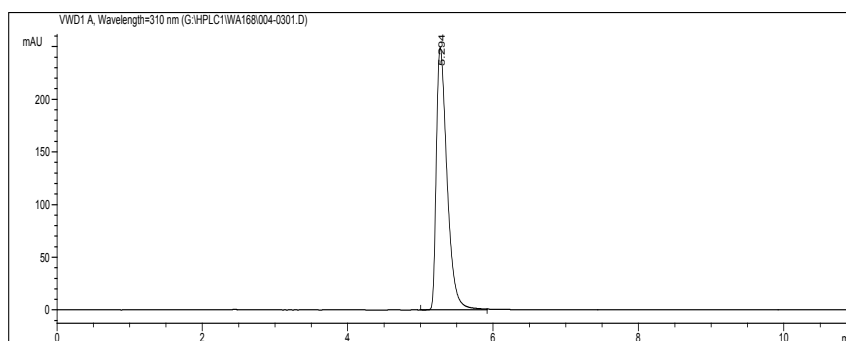
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.02 M sodium dihydrogen phosphate (pH 5.4): acetonitrile = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 216 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1WA168001-0101



The chromatogram of the test solution--- HPLC1WA168004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ondansetron Hydrochloride	5.29	2556.2	6052	/	1.43

# Ondansetron Hydrochloride Injection – 盐酸昂丹司琼注射液

Ondansetron hydrochloride (100559-200301) – Method number WA170

## Assay

Test solution: Add mobile phase to a quantity of the injection fluid to produce the test solution of 0.5 mg/mL.

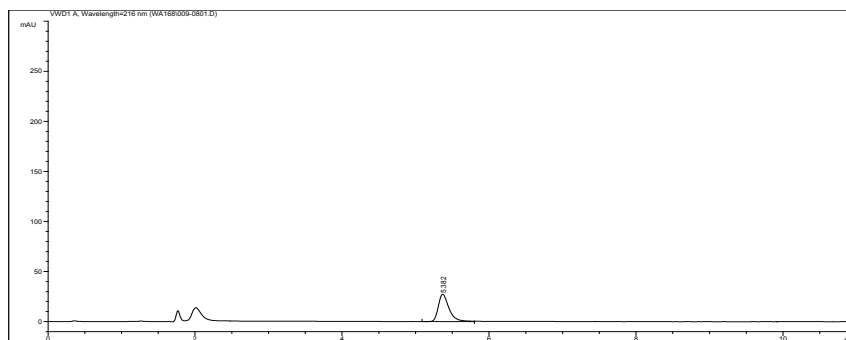
Reference solution: Accurately measure 1 mL of test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

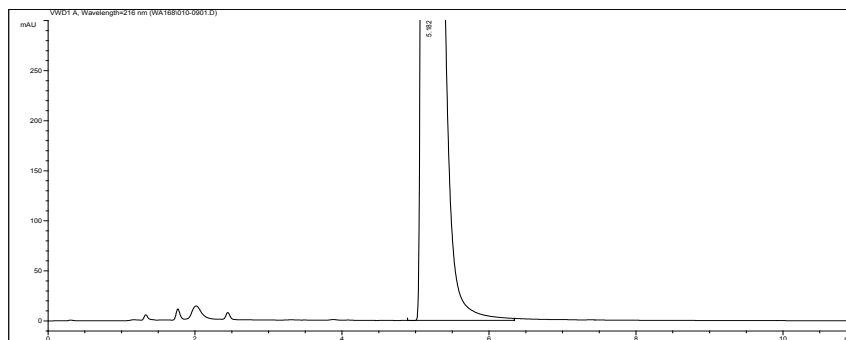
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.02 M sodium dihydrogen phosphate (pH 5.4): acetonitrile = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 216 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA168\009-0801



The chromatogram of the test solution--- HPLC1\WA168\010-0901

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ondansetron Hydrochloride	5.18	29819.0	3758	/	1.61

# Diphenhydramine Hydrochloride Tablets – 盐酸苯海拉明片

Diphenhydramine Hydrochloride (100066-199705) – Method number WA171

## Assay

Test solution: Accurately weigh 20 tablets, removed the coatings and grind to a fine powder. Accurately weigh a quantity, equivalent to about 50 mg of diphenhydramine hydrochloride, in a 100 mL volumetric flask, dissolve and dilute with water to volume, mix well, filter and use the filtrate as the test solution.

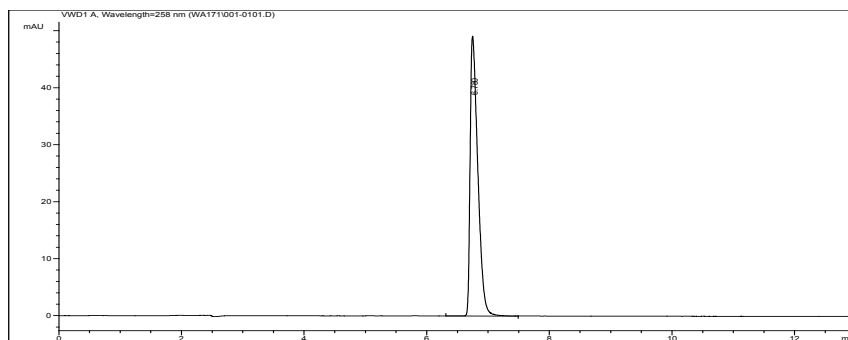
Reference solution: Dissolve an accurately weighed quantity of diphenhydramine hydrochloride CRS in water to produce the reference solution of 0.5 mg/mL.

## Chromatographic conditions

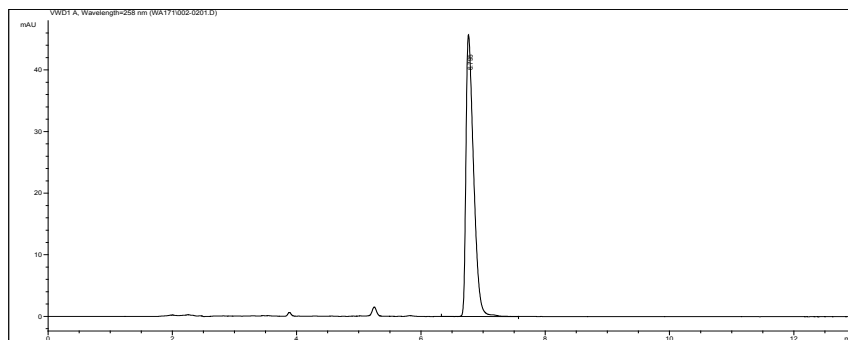
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: acetonitrile: water: triethylamine (adjust pH to 6.5 by glacial acetic acid) = 50:50:0.5
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 258 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA171\001-0101



The chromatogram of the test solution --- HPLC1\ WA171\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Diphenhydramine Hydrochloride	6.79	389.5	12683	/	1.33

# Diphenhydramine Hydrochloride Injection – 盐酸苯海拉明注射液

## Diphenhydramine Hydrochloride (100066-199705) – Method number WR187

### Assay

**Test solution:** Accurately measure a quantity of the injection fluid, equivalent to about 50 mg of diphenhydramine hydrochloride, in a 100 mL volumetric flask, dilute with water to volume, mix well, filter and use the filtrate as the test solution.

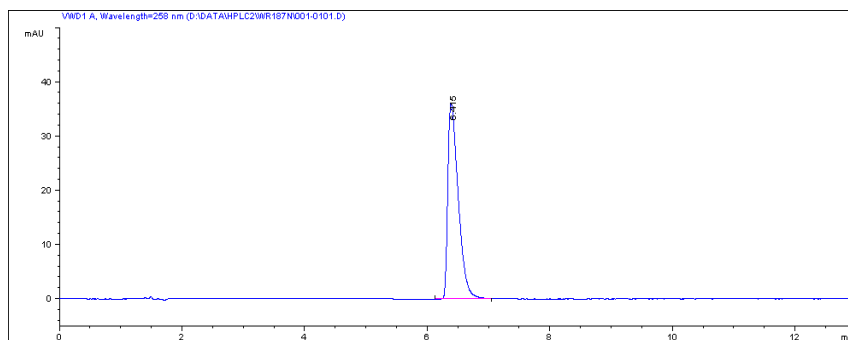
**Reference solution:** Dissolve an accurately weighed quantity of diphenhydramine hydrochloride CRS in water to produce the reference solution of 0.5 mg/mL.

### Chromatographic conditions

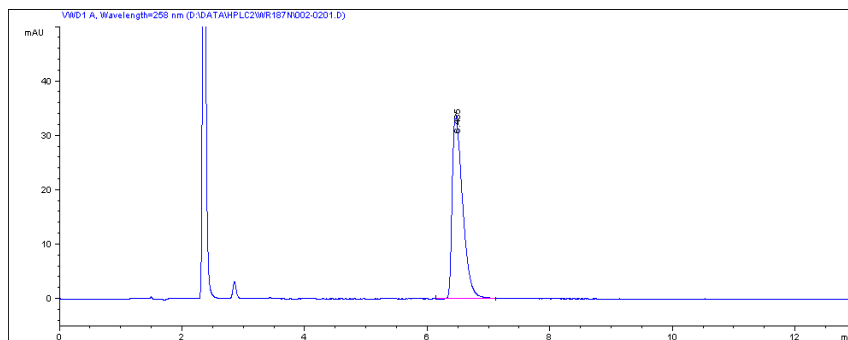
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: acetonitrile: water: triethylamine (adjust pH to 6.5 with glacial acetic acid) = 50:50:0.5
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 258 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR187N001-0101



The chromatogram of the test solution --- HPLC2\WR187N002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Diphenhydramine Hydrochloride	6.48	400.0	5609	/	1.50

# Metformin Hydrochloride – 盐酸二甲双胍

Metformin hydrochloride (100206-200302),

Dicyanodiamide (ACROS) – Method number WR087

## Assay

**Test solution:** Accurately weigh a quantity of the substance, add a quantity of the mobile phase, treat ultrasonically to dissolve the metformin hydrochloride and dilute with mobile phase to produce the test solution of about 0.5 mg/mL.

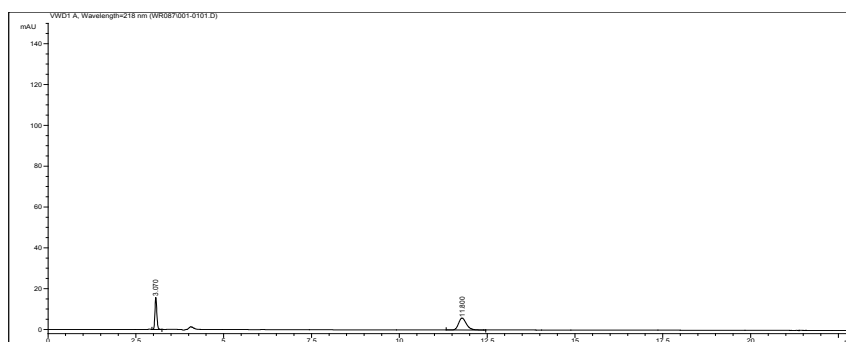
**Reference solution:** Dissolve an accurately weighed quantity of dicyanodiamide CRS in water to produce the reference solution for dicyanodiamide of about 0.1 mg/mL. Accurately measure 0.5 mL each of the test solution and reference solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

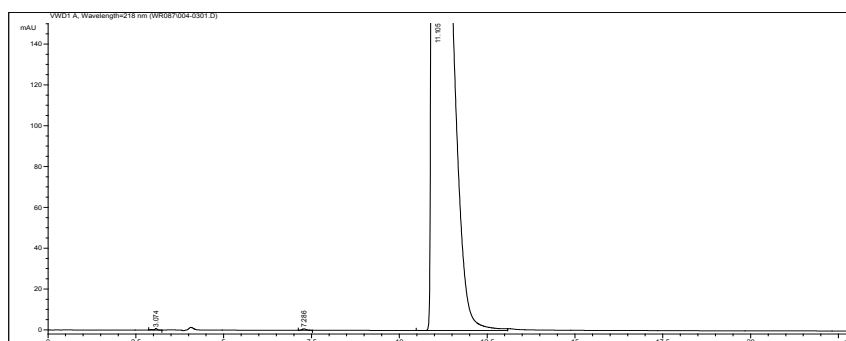
- Column: Agilent ZORBAX 300-SCX 4.6×250 mm, 5 µm (880952-704)
- Mobile phase: 2.3 % ammonium dihydrogen phosphate solution (adjust pH to 3.5 with phosphoric acid)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 40 °C
- Detector wavelength: 218 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC\WR087\001-0101



The chromatogram of the test solution --- HPLC\WR087\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
dicyanodiamide	3.07	2.8	14221	/	0.95
Metformin hydrochloride	10.99	15910.0	3839	7.95	/
Impurity	7.29	5.7	17559	26.2	1.07

# Metformin Hydrochloride Tablets – 盐酸二甲双胍片

Metformin hydrochloride (100206-200302),

Dicyanodiamide (ACROS) – Method number WR088

## Assay

**Test solution:** Accurately weigh a quantity of the powdered tablets, equivalent to about 50 mg of metformin hydrochloride, in a 100 mL volumetric flask, add a quantity of mobile phase, treat ultrasonically to dissolve the metformin hydrochloride, dilute with mobile phase to volume, mix well, filter and use the filtrate as the test solution.

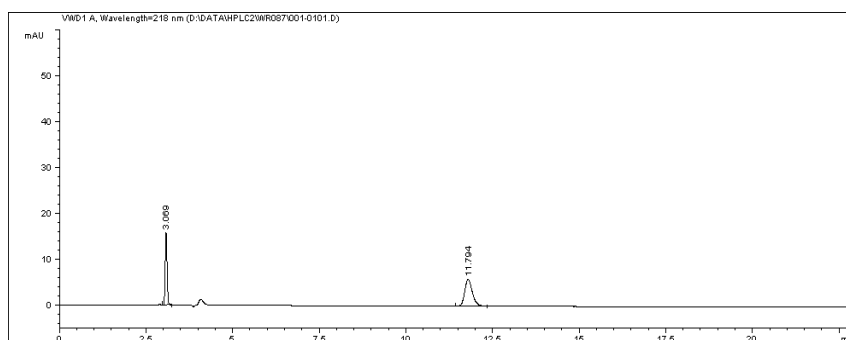
**Reference solution:** Dissolve an accurately weighed quantity of dicyanodiamide CRS in water to produce the reference solution for dicyanodiamide of about 0.1 mg/mL. Accurately measure 0.5 mL each of the test solution and reference solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

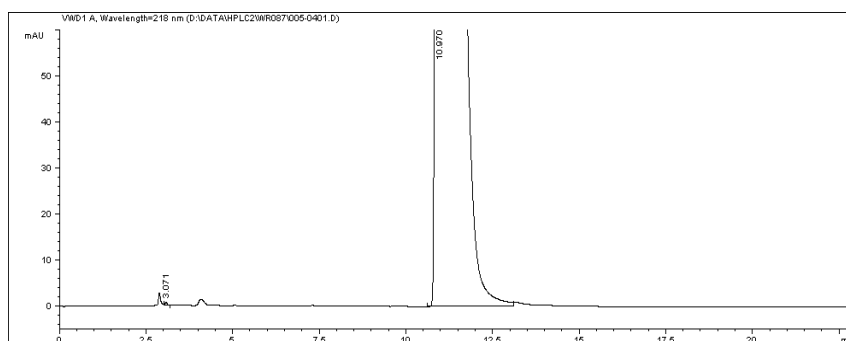
- Column: Agilent ZORBAX 300-SCX 4.6×250 mm, 5 µm (880952-704)
- Mobile phase: 2.3 % ammonium dihydrogen phosphate solution (adjust pH to 3.5 with phosphoric acid)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 40 °C
- Detector wavelength: 218 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution of dicyanodiamide---HPLC2\WR088\001-0101



The chromatogram of the test solution--- HPLC2\WR088\005-0401

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
dicyanodiamide	3.07	2.4	16564	/	1.02
Metformin Hydrochloride	10.91	20891.4	3239	18.3	/



# Valacyclovir Hydrochloride – 盐酸伐昔洛韦

Valacyclovir (100754-200401), Aciclovir (630-200001) – Method number WA295

## Assay

**Test solution:** Accurately weigh about 50 mg in a 100 mL volumetric flask, add a volume of 0.02 mol/L potassium dihydrogen phosphate solution to dissolve, dilute to volume and mix well. Accurately measure a quantity of the solution, dilute with the mobile phase and mix well to produce the test solution of 20 µg/mL.

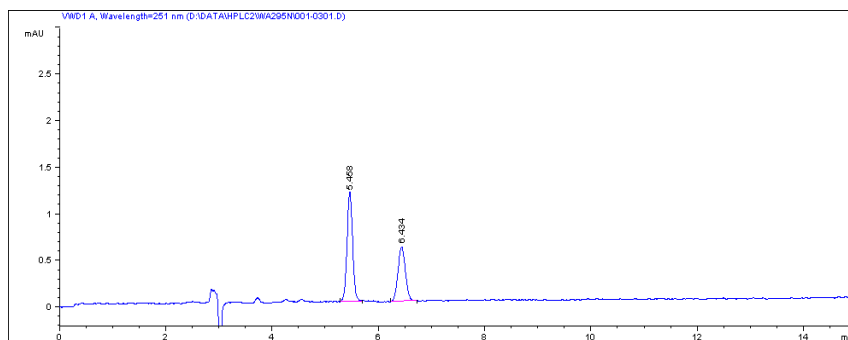
**Reference solution:** Accurately weigh about 15 mg of aciclovir CRS in a 250 mL volumetric flask, add 5 mL of 0.1 mol/L sodium hydroxide solution to dissolve the aciclovir, dilute with water to volume and mix well. Accurately measure 1 mL of the solution in a 200 mL volumetric flask, accurately add 1 mL of the test solution, dilute with mobile phase to volume, mix well and use as the reference solution.

## Chromatographic conditions

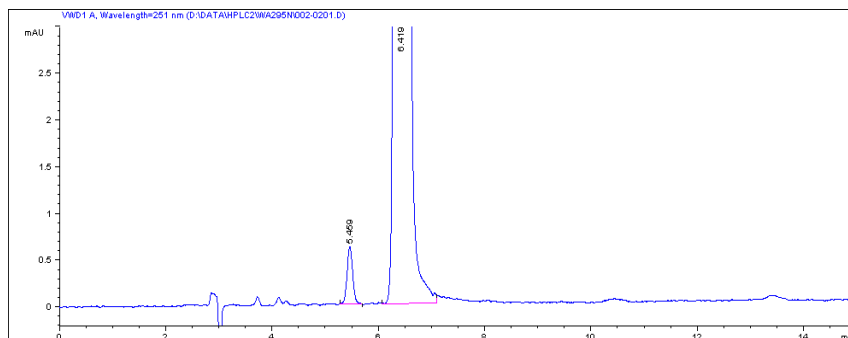
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol:potassium dihydrogen phosphate=20:80
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 251 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA295\N001-0301



The chromatogram of the test solution --- HPLC1\WA295\N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.46	4.6	12966	/	1.06
Valacyclovir	6.42	1055.1	10774	4.4	1.09

# Valacyclovir Hydrochloride Capsules – 盐酸伐昔洛韦胶囊

Valacyclovir hydrochloride (100754-200401) – Method number WA297

## Assay

Test solution: Add a quantity of 0.02 mol/L potassium dihydrogen phosphate solution to an accurately weighed quantity of the well-mixed contents of the capsules to dissolve the valacyclovir hydrochloride, shake thoroughly and filter. Dilute a quantity of the filtrate with mobile phase to produce the test solution of 20 µg/mL.

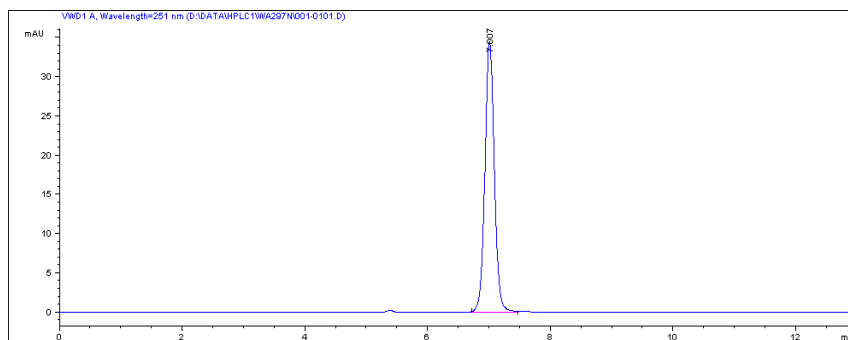
Reference solution: Dissolve and dilute a quantity of valacyclovir CRS in water to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

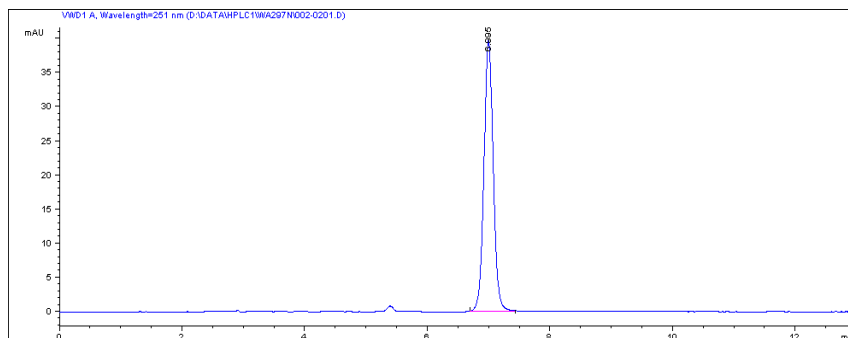
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol: potassium dihydrogen phosphate = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 251 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA297\N001-0101



The chromatogram of the test solution --- HPLC1\WA297\N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Valacyclovir Hydrochloride	7.00	421.7	10358	/	1.03

# Valacyclovir Hydrochloride Tablets – 盐酸伐昔洛韦片

Valacyclovir (100754-200401) – Method number WA296

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 mg of valacyclovir hydrochloride, in a 100 mL volumetric flask, dissolve the valacyclovir hydrochloride in a volume of 0.02 mol/L potassium dihydrogen phosphate solution, dilute with the same solution to volume, mix well and filter. Dilute an accurately measured volume of the filtrate with mobile phase to produce the test solution of 20 µg/mL.

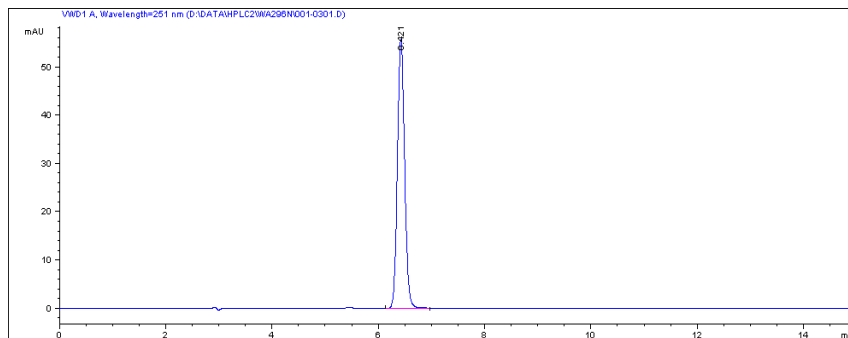
Reference solution: Repeat the procedure using valacyclovir CRS to produce the reference solution, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

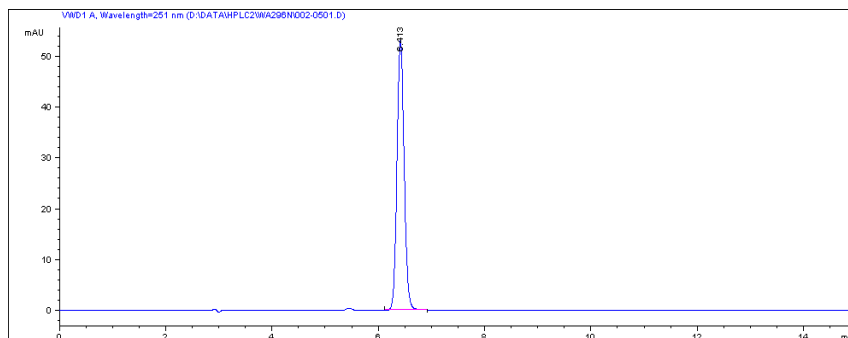
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol: potassium dihydrogen phosphate = 20:80
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 251 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA296N\001-0301



The chromatogram of the test solution --- HPLC1\WA296N\002-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Valacyclovir	6.41	500.6	10749	/	1.07

# Flunarizine Hydrochloride – 盐酸氟桂利嗪

Flunarizine hydrochloride (130451-200302) – Method number WR097

## Assay

Test solution: Dissolve and dilute a quantity with mobile phase to produce the test solution of 0.1 mg/mL.

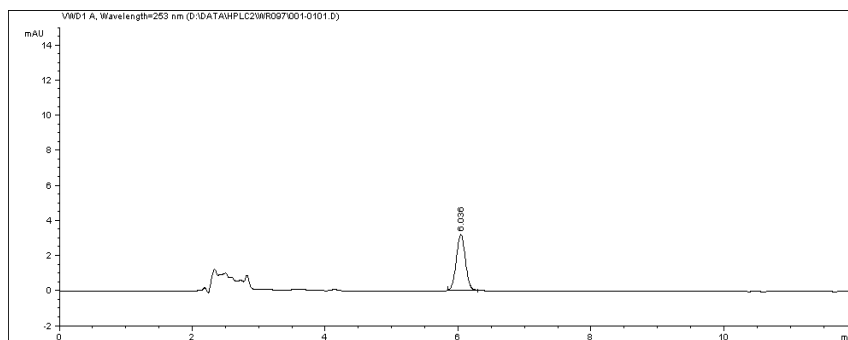
Reference solution: Dilute an accurately measured quantity of the test solution to produce the reference solution of 1 µg/mL.

## Chromatographic conditions

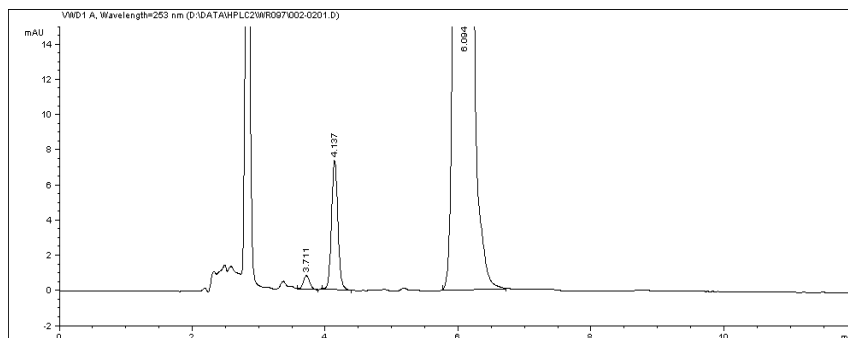
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:phosphate BS (dissolve 1.36 g of potassium dihydrogen phosphate in 1000 mL of water, add 4 mL of triethylamine, adjust pH to 3.5 with phosphoric acid) = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 253 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR097001-0101.D



The chromatogram of the test solution --- HPLC2WR097002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Flunarizine Hydrochloride	6.08	2966.0	7313	8.6	0.95
Impurity1	3.71	4.9	7709	/	1.00
Impurity2	4.14	48.3	9578	2.5	1.07

# Flunarizine Hydrochloride Capsules – 盐酸氟桂利嗪胶囊

Flunarizine hydrochloride (130451-200302) – Method number WR098

## Assay

**Test solution:** Accurately weigh a quantity of the well-mixed contents of the capsules, equivalent to about 10 mg of flunarizine, in a 100 mL volumetric flask, add 10 mL of ethanol, shake thoroughly to dissolve the flunarizine hydrochloride. Dilute with hydrochloric acid solution (dilute 24 mL of dilute hydrochloric acid with water to 1000 mL) to volume, mix well and filter. Discard the initial filtrate and accurately measure 5 mL of the successive filtrate in a 50 mL volumetric flask, dilute with the hydrochloric acid solution to volume, mix well and use as the test solution.

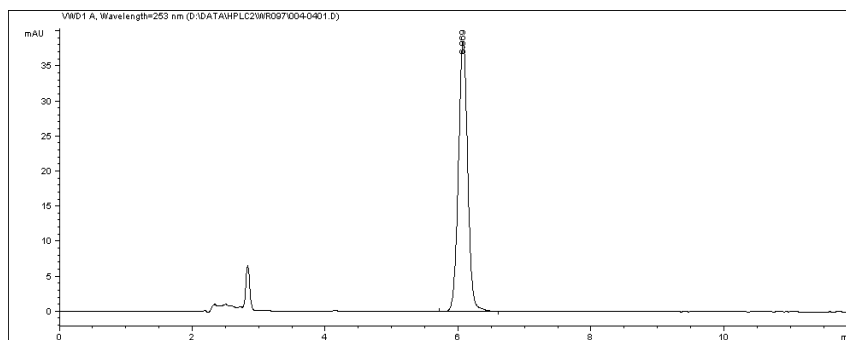
**Reference solution:** Dissolve an accurately weighed quantity of flunarizine hydrochloride CRS dried to constant weight at 105 °C with 10 mL of ethanol, shake well, dilute with the hydrochloric acid solution to produce the reference solution of 12 µg/mL.

## Chromatographic conditions

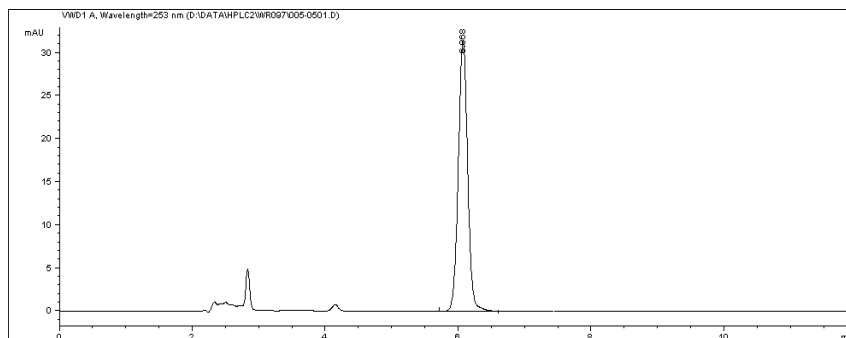
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm 880975-902)
- Mobile phase: methanol: phosphate BS (dissolve 1.36 g of potassium dihydrogen phosphate in 1000 mL of water, add 4 mL of triethylamine, adjust pH to 3.5 with phosphoric acid) = 75: 25
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 253 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR097004-0401.D



The chromatogram of the test solution --- HPLC2WR097005-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Flunarizine Hydrochloride	6.07	307.3	9210	/	1.03

# Granisetron Hydrochloride – 盐酸格拉司琼

Granisetron hydrochloride (10058-200301) – Method number WA173

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase to produce the test solution of 1 mg/mL.

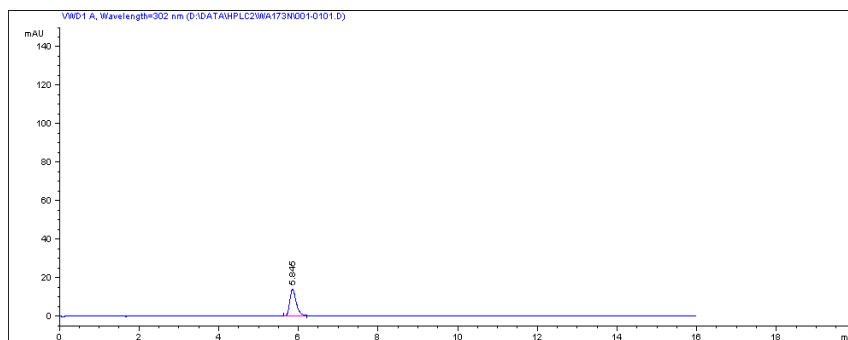
Reference solution: Dilute a quantity of the test solution with mobile phase to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

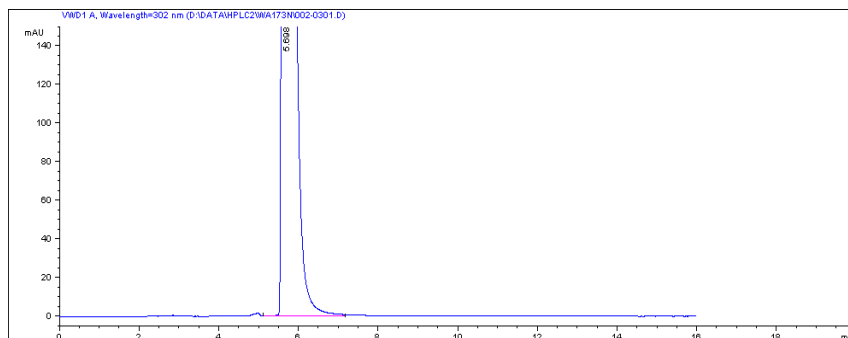
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.05 M sodium acetate BS (containing 0.25 % vol./vol. triethylamine, adjust pH to 6.0 with glacial acetic acid); methanol = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 302 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA173N001-0101



The chromatogram of the test solution--- HPLC2\ WA173N002-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Diphenhydramine Hydrochloride	5.70	19010.0	2936	/	1.62

# Granisetron Hydrochloride Tablets – 盐酸格拉司琼片

Granisetron hydrochloride (10058-200301) – Method number WA174

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder in mobile phase, dilute to volume to produce a solution of 60 µg of granisetron per mL, filter and use the filtrate as the test solution.

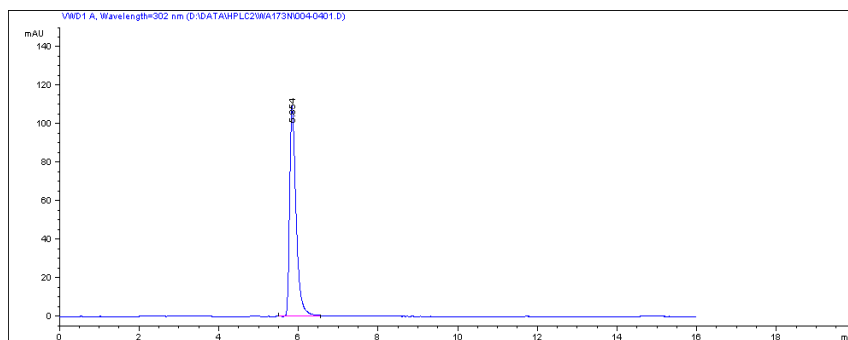
Reference solution: Repeat the procedure using granisetron hydrochloride CRS to produce the reference solution.

## Chromatographic conditions

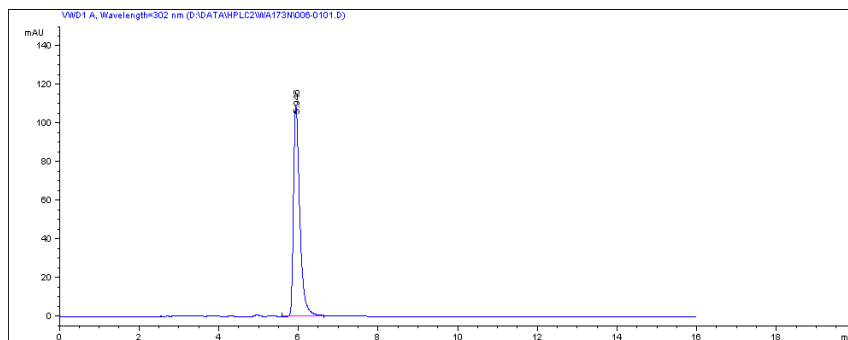
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.05 M sodium acetate BS (containing 0.25 % vol./vol. triethylamine, adjust pH to 6.0 with glacial acetic acid): methanol = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 302 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA173N004-0401



The chromatogram of the test solution--- HPLC2\ WA172N006-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Diphenhydramine Hydrochloride	5.95	1211.6	7194	/	1.44

# Granisetron Hydrochloride Injection – 盐酸格拉司琼注射液

Granisetron hydrochloride (10058-200301) – Method number WA175

## Assay

Test solution: Accurately measure a quantity of the injection fluid and dilute with mobile phase to produce the test solution of about 60 µg of granisetron per mL.

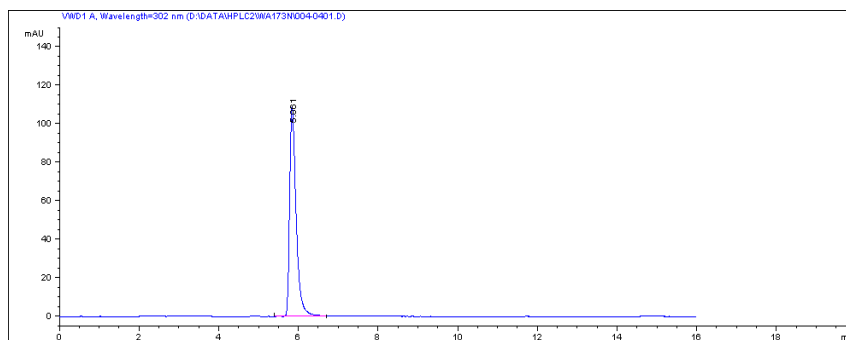
Reference solution: Repeat the procedure using granisetron hydrochloride CRS to produce the reference solution (the conversion factor between granisetron and granisetron hydrochloride is 0.8955).

## Chromatographic conditions

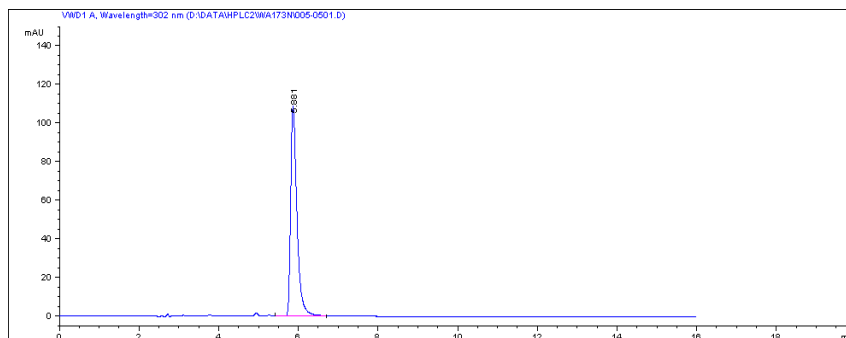
- Column: Agilent ZORBAX XDB-CN 4.6×150 mm, 5 µm (993967-905)
- Mobile phase: 0.05 M sodium acetate BS (containing 0.25 % vol./vol. triethylamine, adjust pH to 6.0 with glacial acetic acid); methanol = 50:50
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 302 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA173N004-0401



The chromatogram of the test solution--- HPLC2\WA173N005-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Diphenhydramine Hydrochloride	5.88	1200.0	7249	/	1.38



# Ciprofloxacin Hydrochloride – 盐酸环丙沙星

Ciprofloxacin (130451-200302) – Method number WR096

## Assay

Test solution: Dissolve a quantity of the substance to produce the test solution containing 0.4 mg/mL.

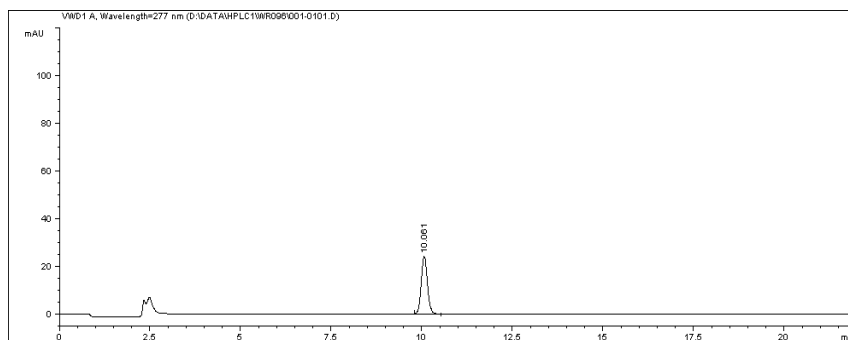
Reference solution: Dissolve a quantity of the substance to produce the reference solution containing 4 µg/mL.

## Chromatographic conditions

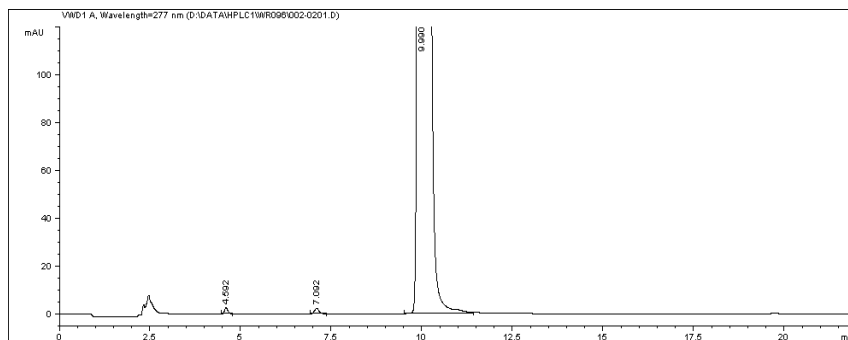
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm 880975-902)
- Mobile phase: 0.05 mol/L citric acid solution: acetonitrile = 85:15 (adjust pH to 3.5 with triethylamine)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 277 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR096\001-0101.D



The chromatogram of the test solution --- HPLC1\WR096\002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ciprofloxacin	9.99	25868.8	12694	9.8	1.51
Impurity1	4.59	16.5	12401	/	1.10
Impurity2	7.09	21.2	14734	12.5	1.14

# Clonidine Hydrochloride Tablets – 盐酸可乐定片

Clonidine hydrochloride (10071-9905) – Method number WR091

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 0.15 mg of clonidine hydrochloride, in a 50 mL volumetric flask, dissolve in a quantity of mobile phase, shake thoroughly for 30 minutes. Dilute with mobile phase to volume, filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

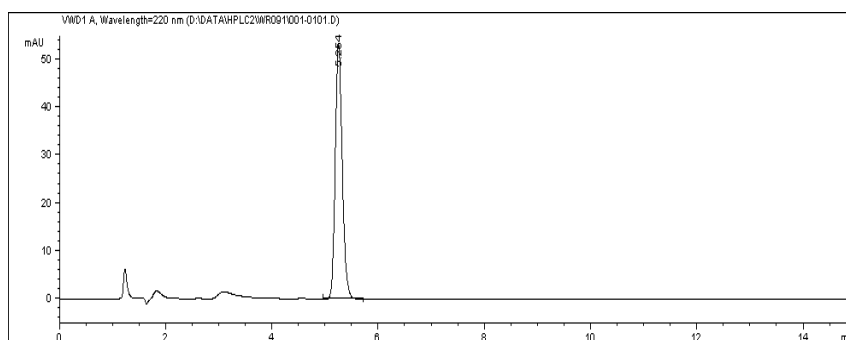
Reference solution: Dilute an accurately weighed quantity of clonidine hydrochloride CRS with mobile phase to produce the reference solution of 3 µg/mL.

## Chromatographic conditions

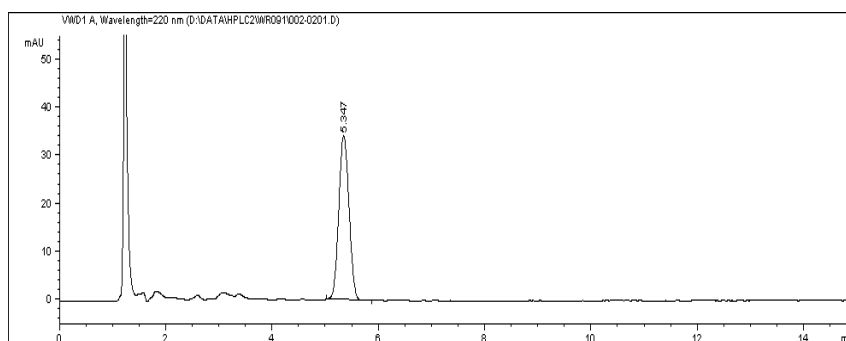
- Column: Agilent ZORBAX XDB-C8 4.6×250 mm, 5 µm (990967-906)
- Mobile phase: 0.22 % sodium octanesulfonate: methanol: phosphoric acid (500:500:1) adjust pH to 3.0 with 1mol/L sodium hydroxide or phosphoric acid)
- Flow rate: 1.0 mL/min
- Injection volume: 50 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WR091\001-0101



The chromatogram of the test solution--- HPLC2\WR091\002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clonidine Hydrochloride	5.35	456.7	3637	/	1.03

# Ranitidine Hydrochloride – 盐酸雷尼替丁

Ranitidine hydrochloride (10163-0004) – Method number WR100N

## Assay

**Internal standard solution:** Dissolve a quantity of indomethacin in methanol to produce the internal standard solution of about 0.3 mg/mL.

**Test solution:** Dissolve an accurately weighed quantity of ranitidine hydrochloride in 50 % methanol solution to produce an intermediate solution of 0.15 mg/mL. Accurately measure 2 mL each of the intermediate solution and the internal standard solution in a 50 mL volumetric flask, dilute with 50 % ethanol solution to volume, mix well and use as the test solution.

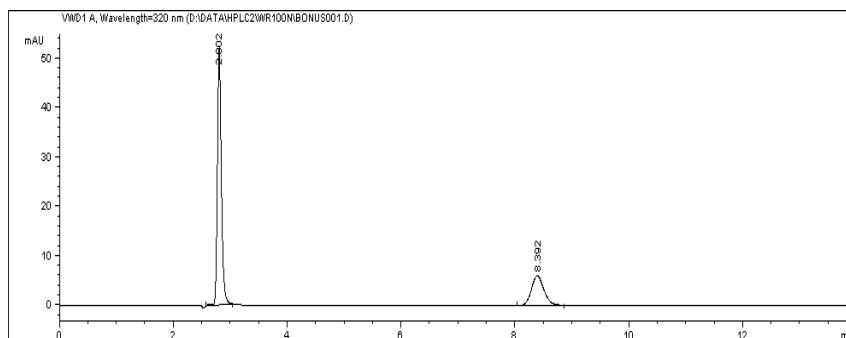
**Reference solution:** Repeat the procedure using ranitidine hydrochloride CRS to produce the reference solution.

## Chromatographic conditions

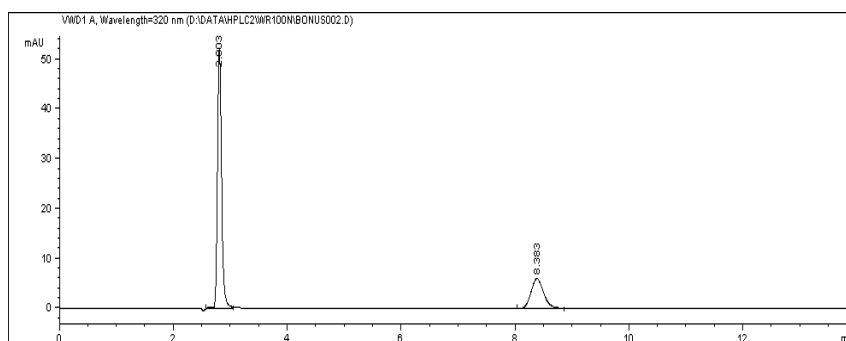
- Column: Agilent ZORBAX Bonus-RP, 4.6x250mm, 5 µm (880688-901)
- Mobile phase: 0.1 mol/L ammonium acetate solution: methanol = 70:30
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 320 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR100NBonus001.D



The chromatogram of the test solution --- HPLC2WR100NBonus002.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Flunarizine Hydrochloride	2.80	262.7	7947	/	1.26
Indometacin	8.38	92.3	7173	21.4	1.16

# Minocycline Hydrochloride – 盐酸米诺环素

Minocycline hydrochloride (130514-200401) – Method number WA299

## Assay

Test solution: Protect from light throughout the procedure. Dissolve a quantity of the substance in water to produce the test solution of 0.5 mg/mL.

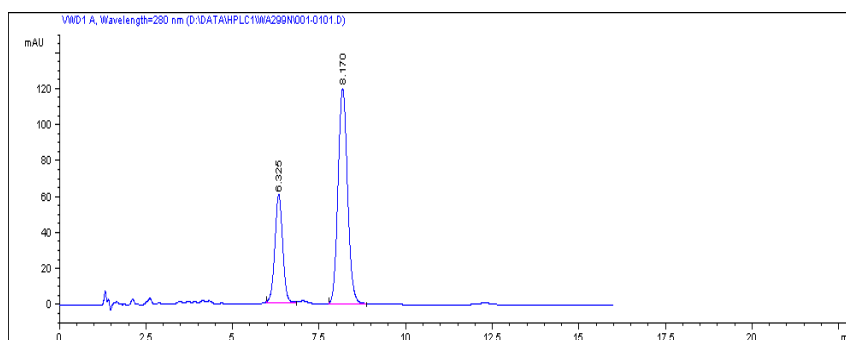
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 5 µg/mL. Accurately weigh 10 mg of minocycline hydrochloride CRS in a 25 mL volumetric flask, add 5 mL of water to dissolve the minocycline hydrochloride, heat in boiling water bath for 60 minutes, allow to cool, dilute with water to volume, mix well and use for the system suitability test.

## Chromatographic conditions

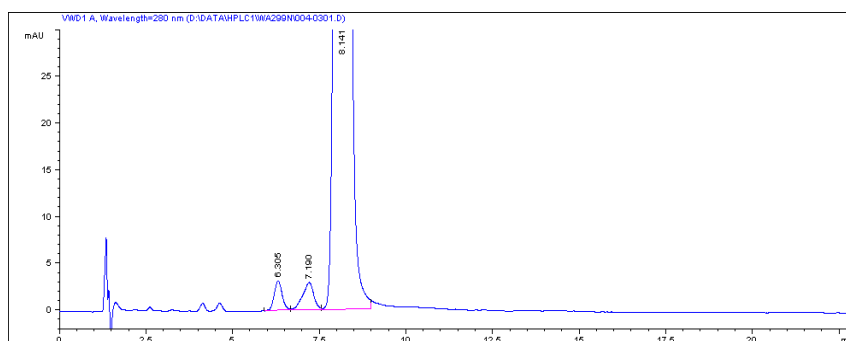
- Column: Agilent ZORBAX Eclipse XDB-C8 4.6×250 mm, 5 µm (993967-906)
- Mobile phase: 0.2 mol/L ammonium acetate solution: N,N-dimethylformamide: tetrahydrofuran = 600:398:2 (with 0.01 mol/L disodium edetate)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability ---HPLC1\WA299N001-0101



The chromatogram of the test solution --- HPLC1\ WA299N004-0301

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Minocycline isomer	6.33	970.8	3840	/	1.00
Minocycline	8.17	2292.4	4290	4.1	1.08

# Minocycline Hydrochloride Capsules – 盐酸米诺环素胶囊

Minocycline hydrochloride (130514-200401) – Method number WA301

## Assay

Test solution: Protect from light throughout the procedure. Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of minocycline, in a 100 mL volumetric flask, add a quantity of water and treat ultrasonically to dissolve the minocycline, dilute to volume, mix well, filter and use the filtrate as the test solution.

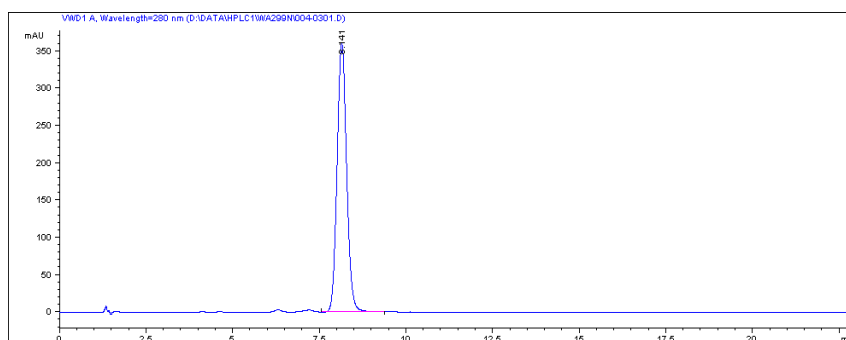
Reference solution: Repeat the procedure using minocycline CRS to produce the reference solution.

## Chromatographic conditions

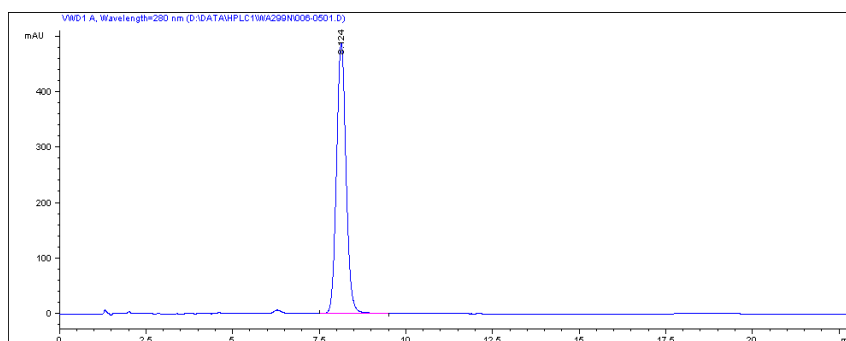
- Column: Agilent ZORBAX Eclipse XDB-C8 4.6×250 mm, 5 µm (993967-906)
- Mobile phase: 0.2 mol/L ammonium acetate solution: N,N-dimethylformamide: tetrahydrofuran = 600:398:2 (with 0.01 mol/L disodium edetate)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA299N004-0301



The chromatogram of the test solution --- HPLC1\ WA299N006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Minocycline	8.12	9319.5	4460	/	1.08

# Minocycline Hydrochloride Capsules – 盐酸米诺环素胶囊

Minocycline hydrochloride (130514-200401) – Method number WA301

## Assay

Test solution: Protect from light throughout the procedure. Dissolve a quantity in water to produce the test solution of 0.5 mg/mL.

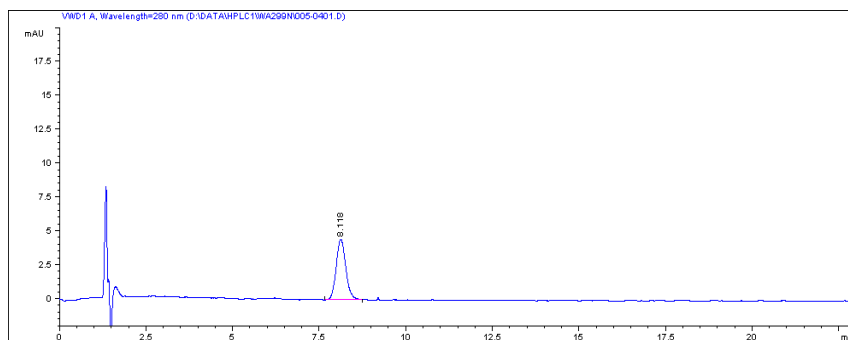
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 5 µg/mL.

## Chromatographic conditions

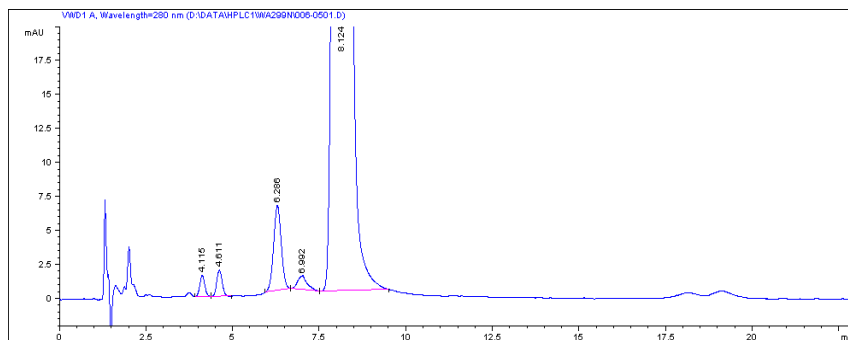
- Column: Agilent ZORBAX Eclipse XDB-C8 4.6×250 mm, 5 µm (993967-906)
- Mobile phase: 0.2 mol/L ammonium acetate solution: N,N-dimethylformamide: tetrahydrofuran = 600:398:2 (with 0.01 mol/L disodium edetate)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA299N005-0401



The chromatogram of the test solution--- HPLC1\ WA299N006-0501

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Minocycline isomer	6.29	96.8	3924	/	1.09
Minocycline	8.12	9319.5	4460	2.3	1.08

# Naphazoline Hydrochloride Nasal Drops – 盐酸萘甲唑林滴鼻液

## Naphazoline hydrochloride (100111-200103) – Method number WR099

### Assay

**Test solution:** Accurately measure 5 mL (of strength 0.1 %) or 10 mL (of strength 0.05 %) of the substance in a 50 mL volumetric flask, dilute with water to volume, mix well and use as the test solution.

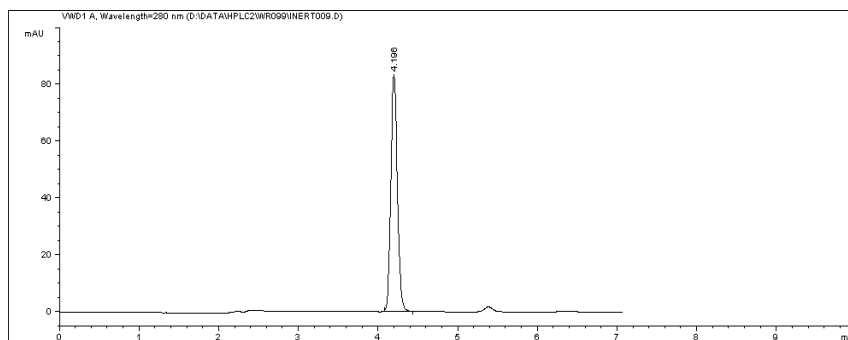
**Reference solution:** Accurately weigh about 25 mg of naphazoline CRS in a 50 mL volumetric flask, dissolve in water, dilute with water to volume and mix well. Accurately measure 5 mL in a 25 mL volumetric flask, dilute with water to volume, mix well and use as the reference solution.

### Chromatographic conditions

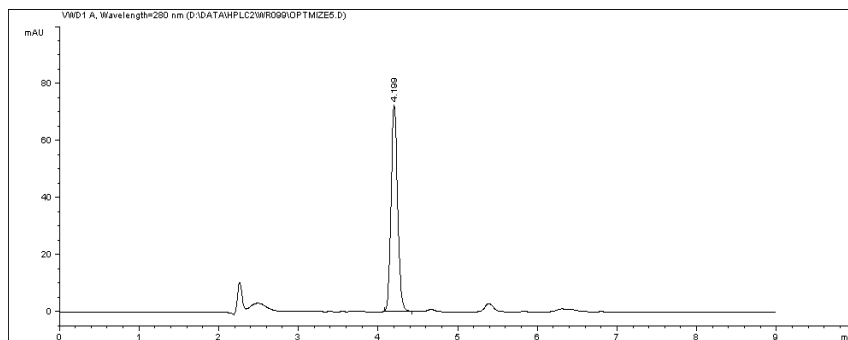
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol:water solution containing triethylamine and phosphoric acid each of 8 % = 47:53
- Flow rate: 1.0 mL/min
- Injection volume: 3 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR099\NERT009



The chromatogram of the test solution --- HPLC2\WR099\OPTIMIZE5

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Naphazoline Hydrochloride	4.20	413.9	11810	/	1.08

# Nicardipine Hydrochloride Injection – 盐酸尼卡地平注射液

Nicardipine hydrochloride (100586-200401) – Method number WA290

## Assay

Test solution: Protect from light throughout the procedure. Dilute a quantity of the injection fluid with mobile phase to produce the test solution of 50 µg/mL.

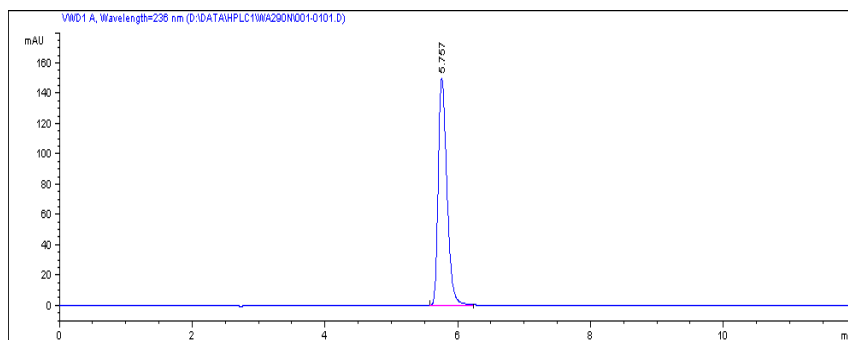
Reference solution: Repeat the procedure using nicardipine hydrochloride CRS to produce the reference solution.

## Chromatographic conditions

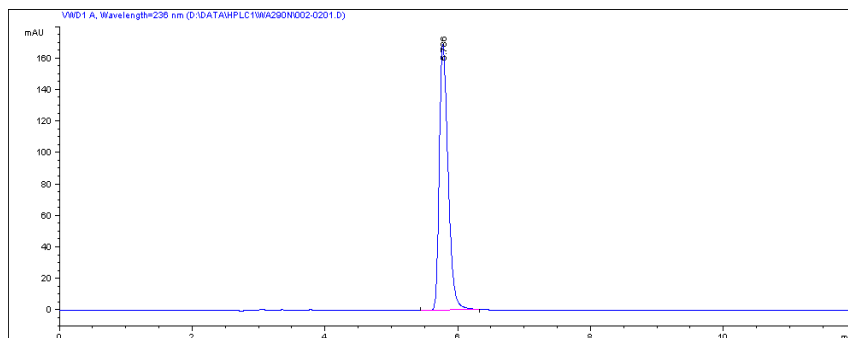
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.01 mol/L potassium dihydrogen phosphate solution:methanol = 25:75
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 236 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA290N001-0101



The chromatogram of the test solution --- HPLC1\ WA290N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP Tf
Nicardipine Hydrochloride	5.79	1577.3	8559	/	1.24



# Nicardipine Hydrochloride Injection – 盐酸尼卡地平注射液

Nicardipine hydrochloride (100586-200401) – Method number WA290

## Assay

Test solution: Protect from light throughout the procedure. Dilute a quantity of the injection with mobile phase to produce the test solution containing 50 µg/mL.

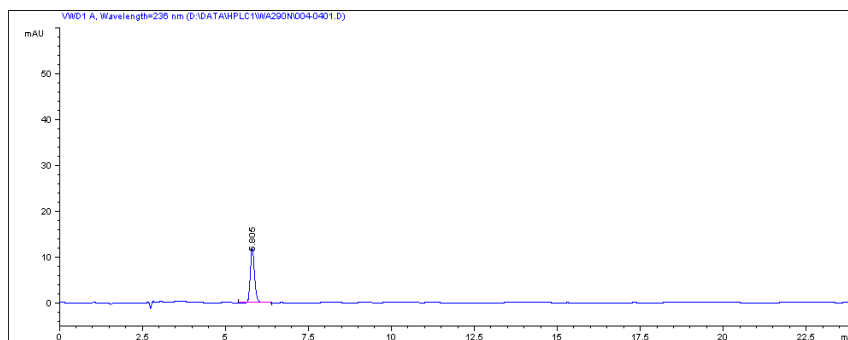
Reference solution: Dilute an accurately measured quantity of the test solution to produce the reference solution containing 2 µg/mL.

## Chromatographic conditions

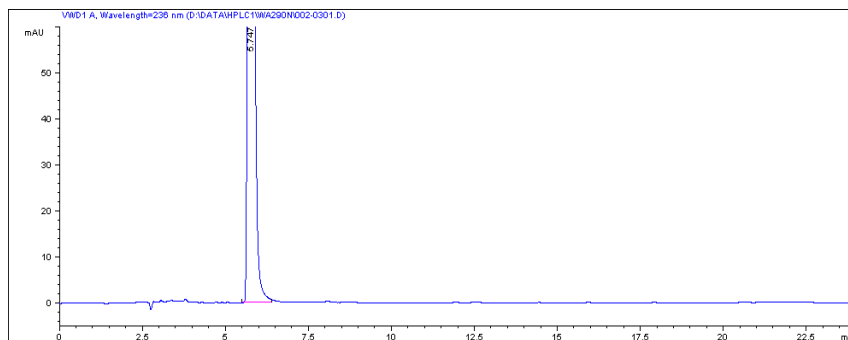
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.01 mol/L potassium dihydrogen phosphate solution:methanol = 25:75
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 236 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA290N004-0401



The chromatogram of the test solution --- HPLC1\ WA290N002-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Nicardipine Hydrochloride	5.75	3141.8	6340	/	1.36

# Paroxetine Hydrochloride Tablets – 盐酸帕罗西汀片

Paroxetine Hydrochloride (100357-200301) – Method number WA302

## Assay

Test solution: Put 10 tablets in a 250 mL volumetric flask, add 70 mL of water and 5 mL of 0.01 mol/L hydrochloric acid solution, treat ultrasonically for 15 minutes, shake occasionally, allow to cool to room temperature, dilute with isopropanol to volume, mix well and filter. Accurately measure 10 mL the filtrate in a 100 mL volumetric flask, dilute with 70 % isopropanol to volume, mix well and use as the test solution.

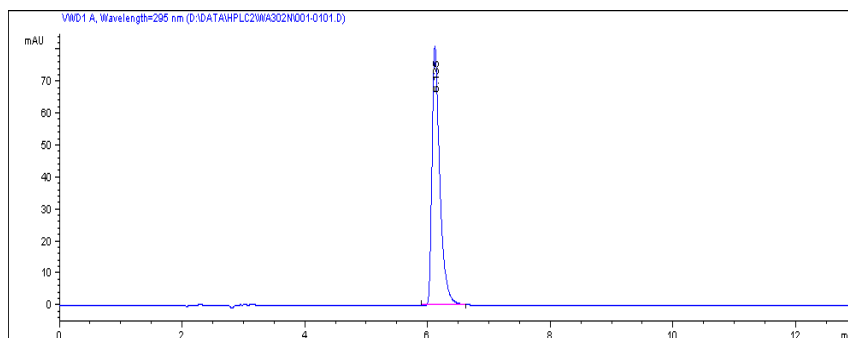
Reference solution: Dissolve an accurately weighed quantity of paroxetine hydrochloride CRS, equivalent to about 20 mg of paroxetine, in a 250 mL volumetric flask, add 10 mL of 0.01 mol/L hydrochloric acid solution and a quantity of 70 % isopropanol, shake well to dissolve the paroxetine hydrochloride, dilute with 70 % isopropanol to volume, mix well and use as the reference solution.

## Chromatographic conditions

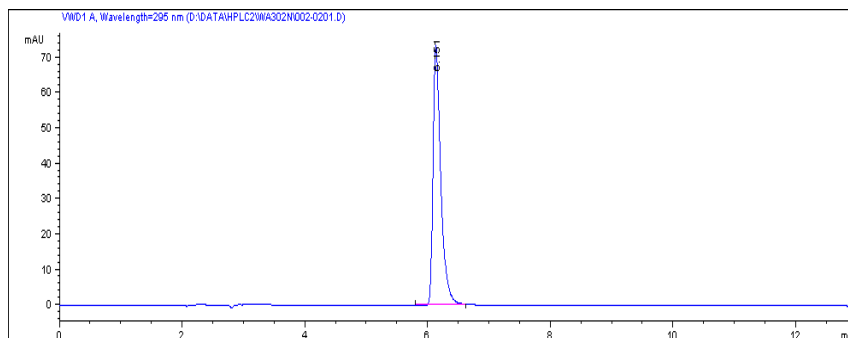
- Column: Agilent ZORBAX XDB-CN 4.6×250 mm, 5 µm (990967-905)
- Mobile phase: acetonitrile: phosphate BS (dissolve 4.9 g of phosphoric acid in 800 mL of water, adjust pH to 6.0 with 0.1 mol/L sodium hydroxide, dilute with water to 1000 mL) = 60:40
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 295 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WA302N001-0101



The chromatogram of the test solution --- HPLC2WA302N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Paroxetine hydrochloride	6.15	649.2	10829	/	1.41

# Tramadol Hydrochloride – 盐酸曲马多

Tramadol hydrochloride (0303-9613),

Tramadol hydrochloride-cis (171255-200401) – Method number WR092

## Assay

Test solution: Dissolve a quantity with the mobile phase to produce the test solution of 2 mg of tramadol hydrochloride per mL.

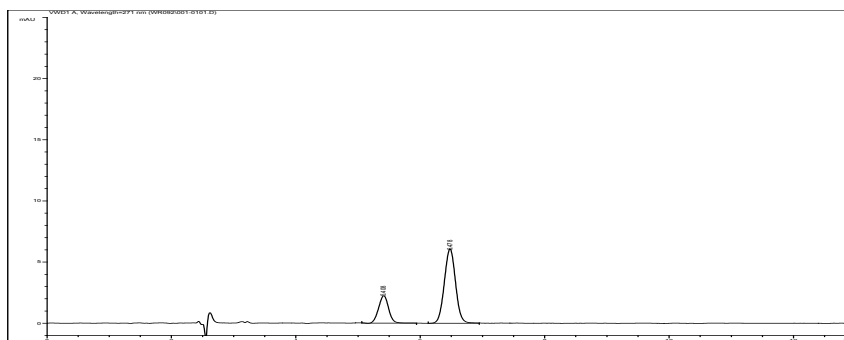
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, accurately add 3 mL of a solution of tramadol Hydrochloride-cis (dissolve a quantity of tramadol Hydrochloride-cis CRS with mobile phase to produce a solution of 0.2 mg/mL), dilute with mobile phase to volume and use as the reference solution.

## Chromatographic conditions

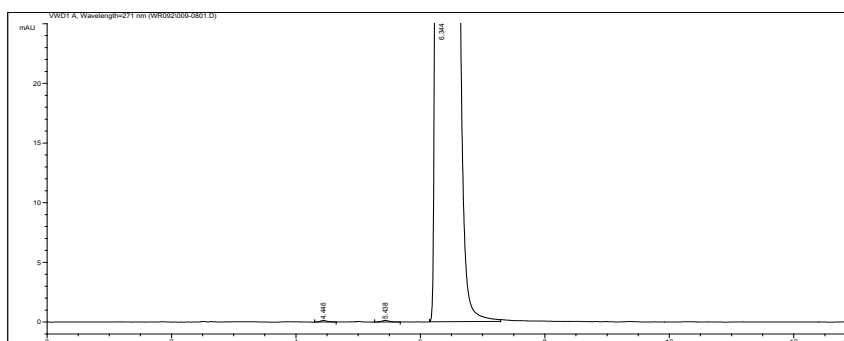
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH4.5):methanol=65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092001-0101.D



The chromatogram of the test solution --- HPLC2WR092009-0801.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tramadol Hydrochloride-cis	5.44	1.0	12069	5.1	1.13
Tramadol Hydrochloride	6.33	7573.2	5751	3.4	1.93
Impurity	4.44	1.0	8973	/	1.26

# Tramadol Hydrochloride Sustained-release Capsules

Tramadol hydrochloride (171242-200302) – Method number WA165

盐酸曲马多缓释胶囊

## Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of tramadol hydrochloride, in a 100 mL volumetric flask and add a quantity of mobile phase. Heat in a hot water bath and shake to dissolve the tramadol hydrochloride, allow to cool to room temperature and dilute with mobile phase to volume, mix well, filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

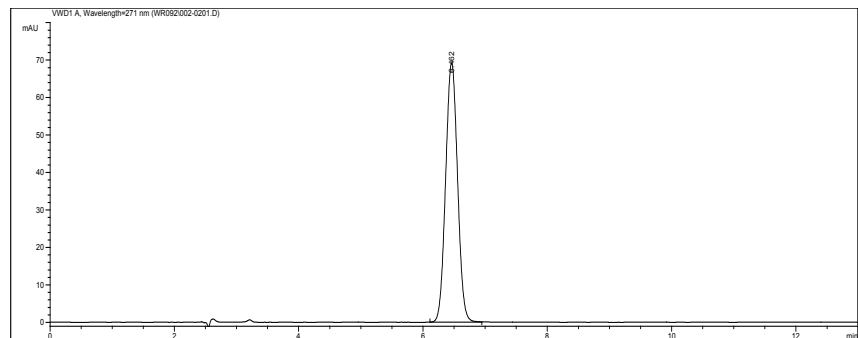
Reference solution: Repeat the procedure using tramadol hydrochloride CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

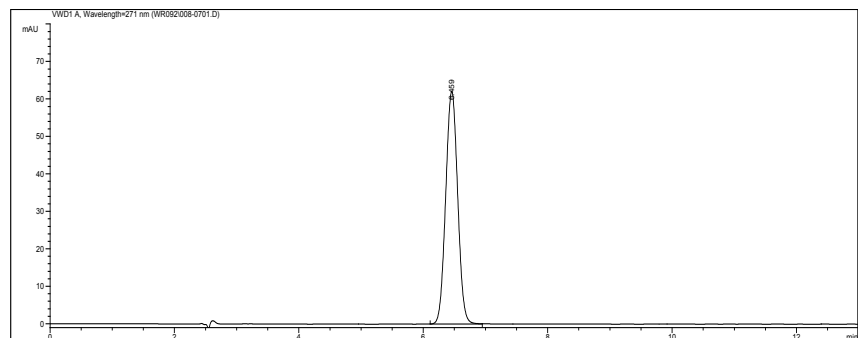
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5): methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092002-0201.D



The chromatogram of the test solution--- HPLC2WR092008-0701.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Tramadol Hydrochloride	6.46	828.8	5304	/	1.04

# Tramadol Hydrochloride Sustained release Capsules

Tramadol hydrochloride (171242-200302) – Method number WA165

盐酸曲马多缓释胶囊

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase, heat in a hot water bath and shake to dissolve the tramadol hydrochloride, allow to cool to room temperature, dilute to produce a solution containing 2 mg of tramadol hydrochloride per mL, millipore membrane (0.45 µm) and use the filtrate as the test solution.

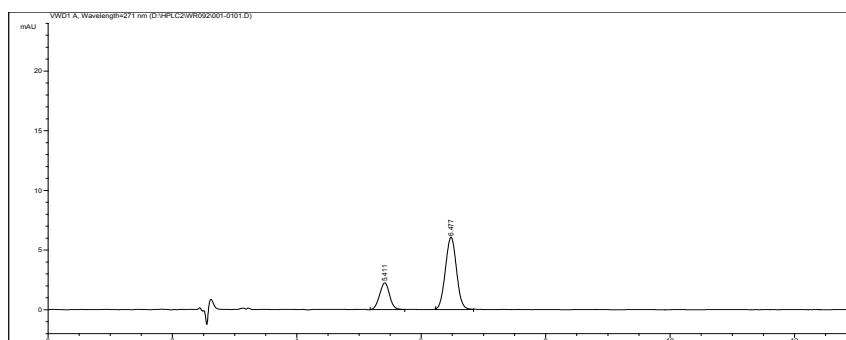
Reference solution: Dilute a quantity of Z-tramadol hydrochloride CRS with mobile phase to produce the reference solution of 0.2 mg/mL. Accurately measure 1 mL of the test solution and 3 mL of the reference solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use for the system suitability test.

## Chromatographic conditions

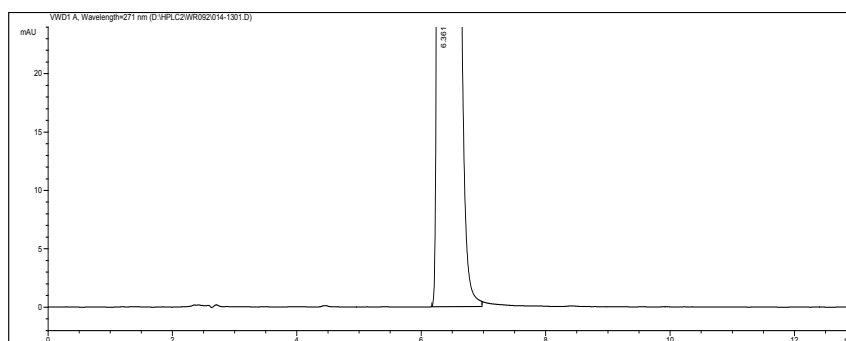
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5) : methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC2\WR092\001-0101.D



The chromatogram of the test solution--- HPLC2\WR092\014-1301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tramadol Hydrochloride-cis	5.41	25.2	5414	/	1.02
Tramadol Hydrochloride-trans	6.48	75.6	6325	3.4	1.03

# Tramadol Hydrochloride Sustained-release Tablets

Tramadol hydrochloride (171242-200302) – Method number WA164

盐酸曲马多缓释片

## Assay

Test solution: Accurately weigh 10 tablets and cut into pieces. Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of tramadol hydrochloride, in a 100 mL volumetric flask and add a quantity of mobile phase. Heat in a hot water bath and shake to dissolve the tramadol hydrochloride, allow to cool to room temperature, dilute with mobile phase to volume, mix well, filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

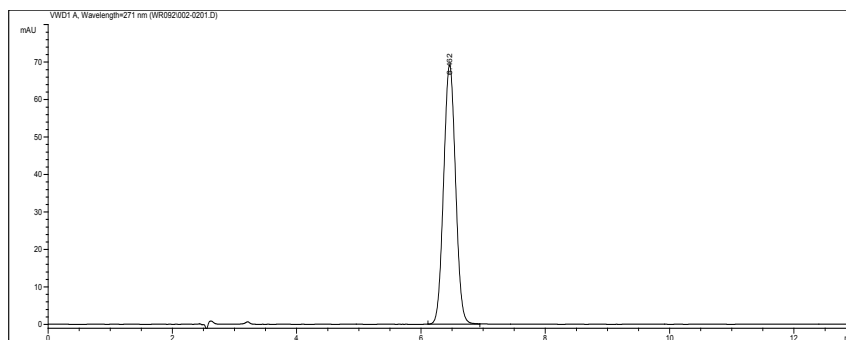
Reference solution: Repeat the procedure using tramadol hydrochloride CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

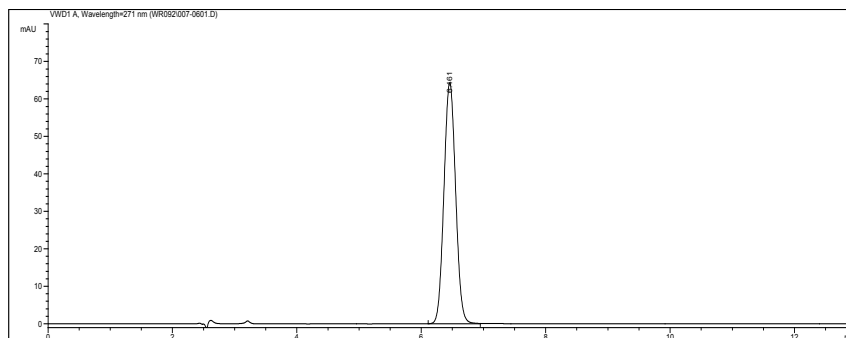
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5) : methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092002-0201.D



The chromatogram of the test solution--- HPLC2WR092007-0601.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Tramadol Hydrochloride	6.46	838.2	5695	/	1.05

# Tramadol Hydrochloride Sustained-release Tablets

Tramadol hydrochloride (171242-200302) – Method number WA164

盐酸曲马多缓释片

## Assay

Test solution: Dissolve a quantity of the powdered tablets in mobile phase. Heat in a hot water bath and shake to dissolve the tramadol hydrochloride. Allow to cool to room temperature, dilute with mobile phase to produce a solution of 2 mg of tramadol hydrochloride per mL, mix well, filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

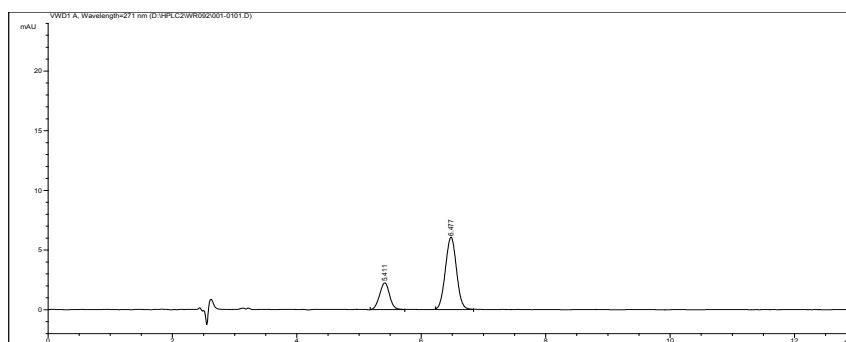
Reference solution: Dilute a quantity of Z-tramadol hydrochloride CRS with mobile phase to produce the reference solution of 0.2 mg/mL. Accurately measure 1 mL of the test solution and 3 mL of the reference solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use for the system suitability test.

## Chromatographic conditions

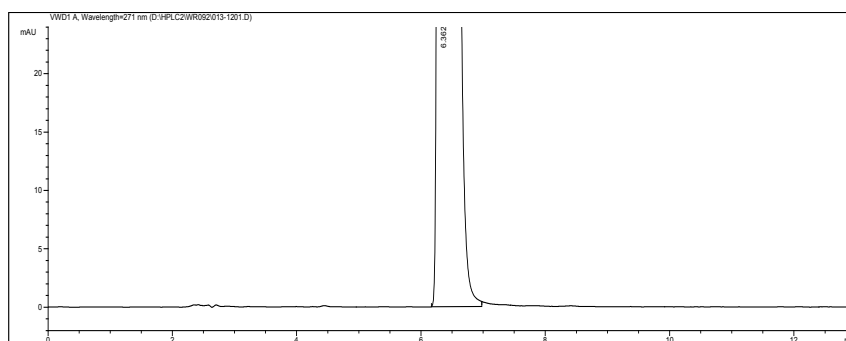
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5) : methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC2\WR092\001-0101.D



The chromatogram of the test solution--- HPLC2\WR092\013-1201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tramadol Hydrochloride-cis	5.41	25.2	5414	/	1.02
Tramadol Hydrochloride-trans	6.48	75.6	6325	3.4	1.03

# Tramadol Hydrochloride Tablets – 盐酸曲马多片

Tramadol hydrochloride (0303-9613) – Method number WR093

## Assay

Test solution: Dissolve a quantity of the powder in mobile phase to produce a solution of 2 mg of tramadol hydrochloride per mL, mix well, filter and use the filtrate as the test solution.

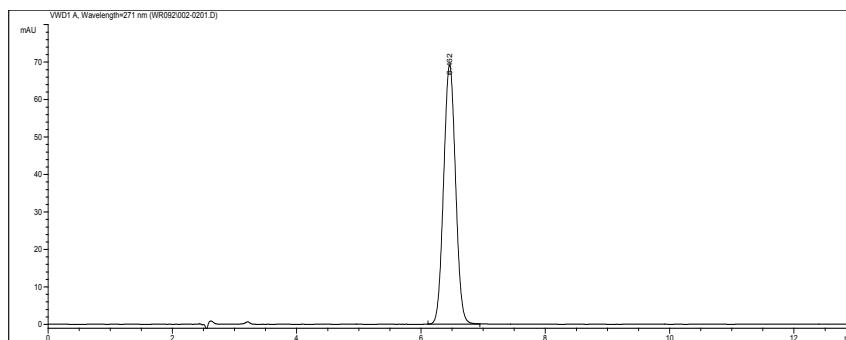
Reference solution: Dissolve a quantity of tramadol hydrochloride-cis CRS in mobile phase to produce a solution of 0.2 mg/mL. Accurately measure 3 mL of this solution in a 100 mL volumetric flask, accurately add 1 mL of the test solution, dilute with mobile phase to volume and use as the reference solution.

## Chromatographic conditions

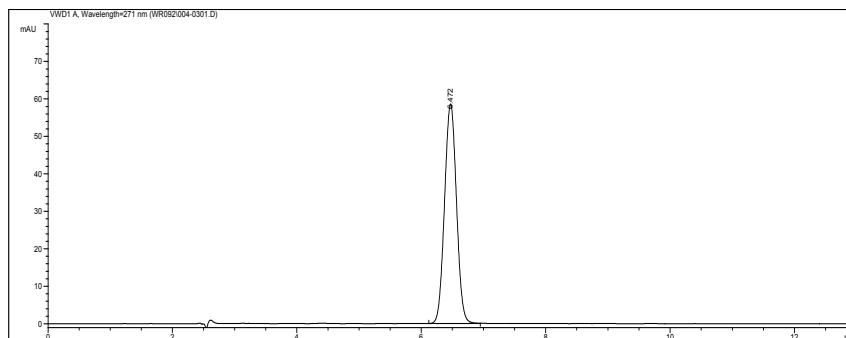
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5):methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092002-0201.D



The chromatogram of the test solution --- HPLC2WR092004-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Tramadol Hydrochloride	6.47	781.7	5206	/	1.04



# Tramadol Hydrochloride Tablets – 盐酸曲马多片

Tramadol hydrochloride (0303-9613) – Method number WR093

## Assay

Test solution: Accurately weigh 20 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 mg of tramadol hydrochloride, in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well, filter and use the filtrate as the test solution.

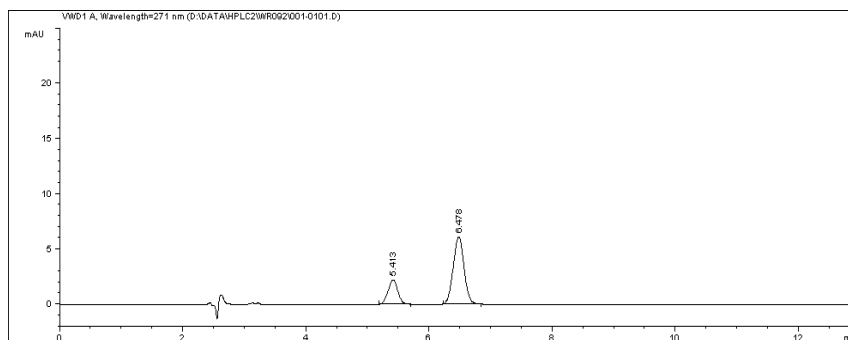
Reference solution: Repeat the procedure using tramadol hydrochloride CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

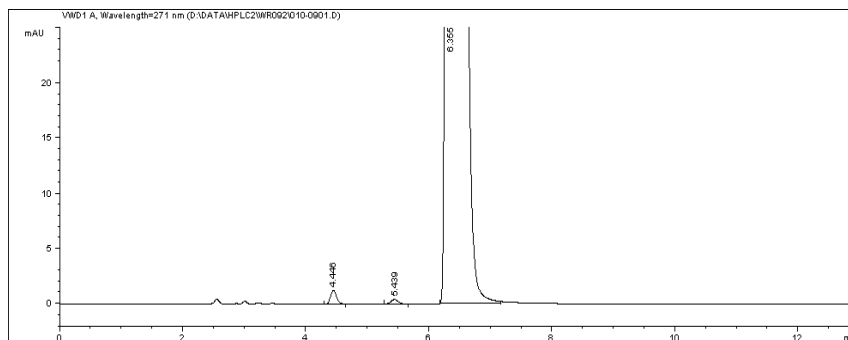
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5): methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092001-0101.D



The chromatogram of the test solution--- HPLC2WR092010-0901.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Tramadol Hydrochloride-cis	5.44	3.6	9784	5.0	1.03
Tramadol Hydrochloride	6.36	6605.7	6246	3.4	1.86
Impurity	4.45	8.1	10296	/	1.15

# Tramadol Hydrochloride Suppositories – 盐酸曲马多栓

Tramadol hydrochloride (171242-200302) – Method number WA163

## Assay

Test solution: Cut 10 suppositories into pieces and mix well. Accurately weigh a quantity, equivalent to about 50 mg of tramadol hydrochloride, in a 100 mL volumetric flask, add a quantity of mobile phase, heat in a hot water bath and shake to dissolve the tramadol hydrochloride, allow to cool to room temperature, dilute with mobile phase to volume, mix well, filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

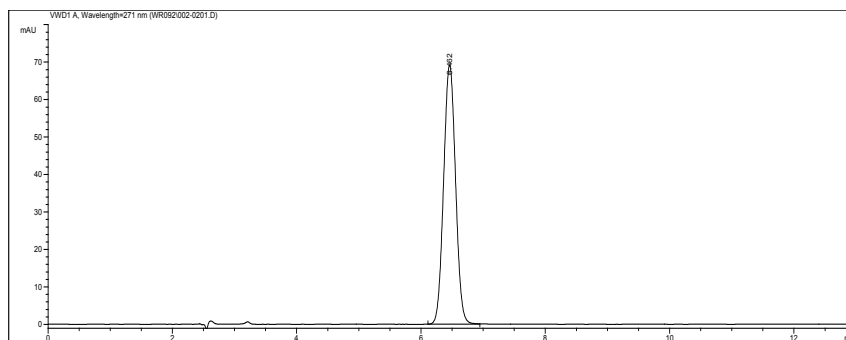
Reference solution: Repeat the procedure using tramadol hydrochloride CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

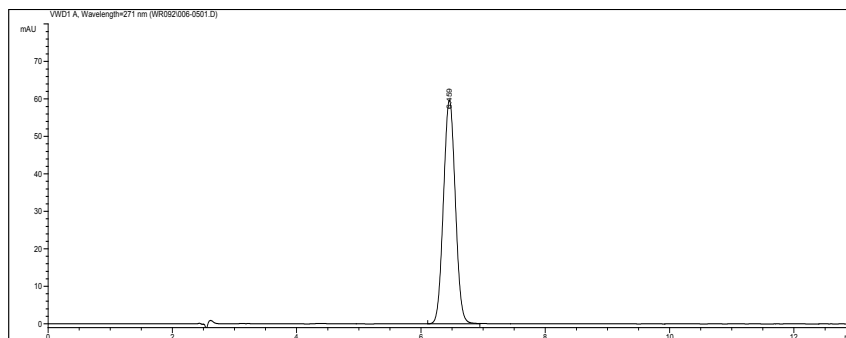
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5): methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092002-0201.D



The chromatogram of the test solution--- HPLC2WR092006-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tramadol Hydrochloride	6.46	791.5	5430	/	1.04

# Tramadol Hydrochloride Suppositories – 盐酸曲马多栓

Tramadol hydrochloride (171242-200302) – Method number WA163

## Assay

Test solution: Dissolve a quantity of the pieces in mobile phase, heat in a hot water bath and shake to dissolve the tramadol hydrochloride, allow to cool to room temperature, dilute to produce a solution containing 2 mg of tramadol hydrochloride per mL, filter through a millipore membrane (0.45 µm) and use the filtrate as the test solution.

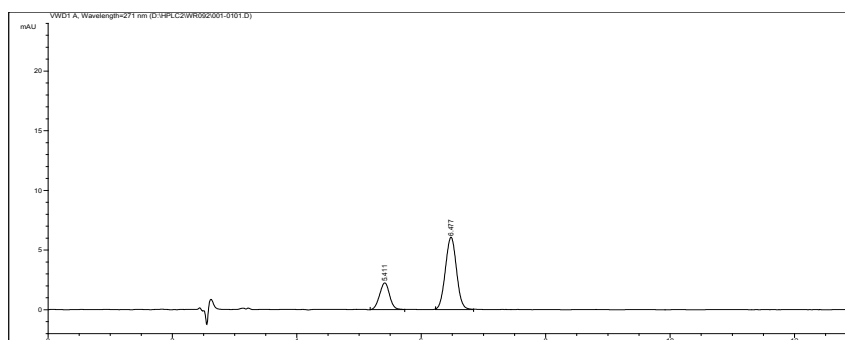
Reference solution: Dilute a quantity of Z-tramadol hydrochloride CRS with mobile phase to produce the reference solution of 0.2 mg/mL. Accurately measure 1 mL of the test solution and 3 mL of the reference solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use for the system suitability test.

## Chromatographic conditions

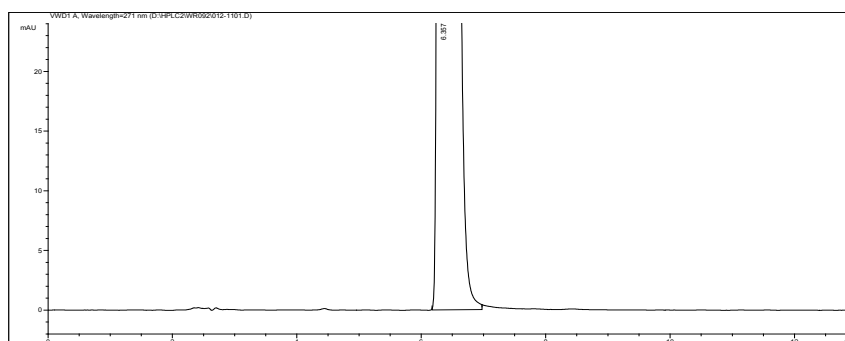
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5): methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC2\WR092\001-0101.D



The chromatogram of the test solution --- HPLC2\WR092\012-1101.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tramadol Hydrochloride-cis	5.41	25.2	5414	/	1.02
Tramadol Hydrochloride-trans	6.48	75.6	6325	3.4	1.03

# Tramadol Hydrochloride Injection – 盐酸曲马多注射液

Tramadol hydrochloride (0303-9613) – Method number WR094

## Assay

Test solution: Dissolve a quantity of the injection fluid in mobile phase to produce a solution of 2 mg of tramadol hydrochloride per mL, mix well, filter and use the filtrate as the test solution.

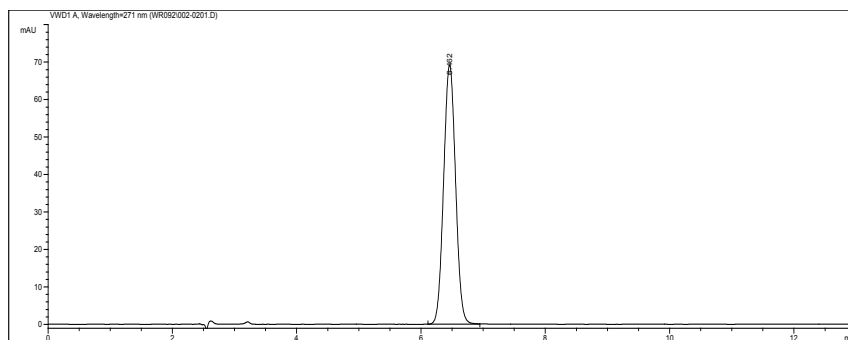
Reference solution: Dissolve a quantity of tramadol hydrochloride-cis CRS in mobile phase to produce a solution of 0.2 mg/mL. Accurately measure 3 mL of this solution in a 100 mL volumetric flask, accurately add 1 mL of the test solution, dilute with mobile phase to volume and use as the reference solution.

## Chromatographic conditions

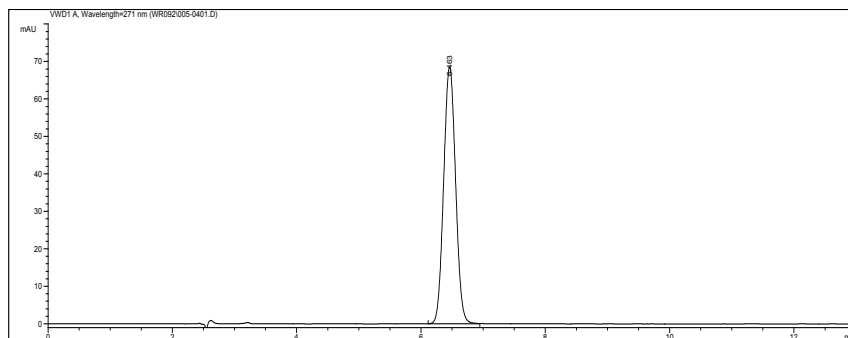
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5): methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092002-0201.D



The chromatogram of the test solution--- HPLC2WR092005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Tramadol Hydrochloride	6.46	914.7	5192	/	1.05

# Tramadol Hydrochloride Injection – 盐酸曲马多注射液

Tramadol hydrochloride (0303-9613),

Tramadol hydrochloride-cis (171255-200401) – Method number WR094

## Assay

Test solution: Accurately measure a quantity of the injection fluid, equivalent to about 50 mg of tramadol hydrochloride, in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well, filter and use the filtrate as the test solution.

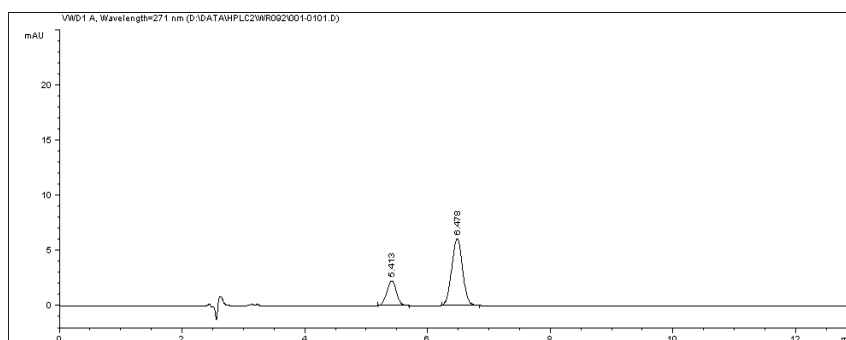
Reference solution: Repeat the procedure using tramadol hydrochloride CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

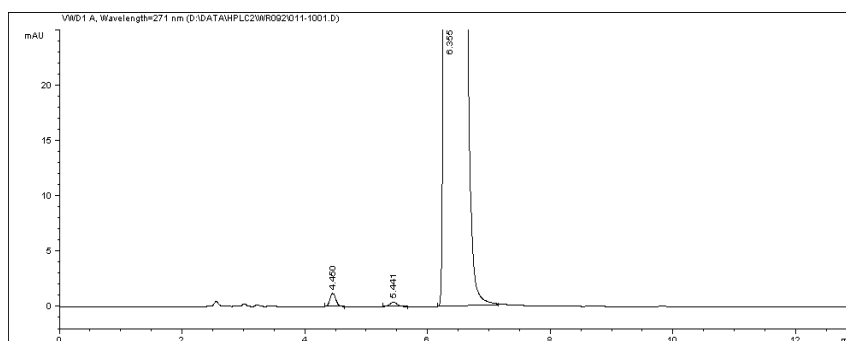
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: acetic acid-sodium acetate BS (pH 4.5): methanol = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 271 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR092002-0201.D



The chromatogram of the test solution--- HPLC2WR092005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Tramadol Hydrochloride-cis	5.44	3.5	10298	5.1	1.06
Tramadol Hydrochloride	6.36	6610.7	6245	3.4	1.84
Impurity	4.45	8.1	10314	/	1.12

# Norvancomycin Hydrochloride – 盐酸去甲万古霉素

Norvancomycin hydrochloride (3389302) – Method number WR090

## Assay

Test solution: Dissolve a quantity in water and dilute to produce the test solution containing 2 mg/mL.

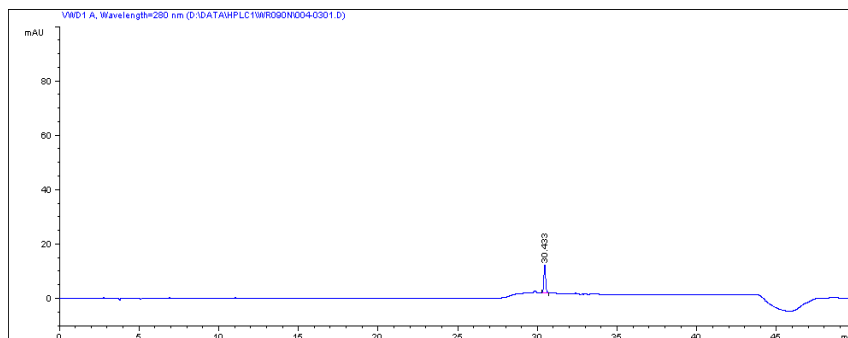
Reference solution: Dissolve a quantity in water and dilute to produce the reference solution containing 20 µg/mL.

## Chromatographic conditions

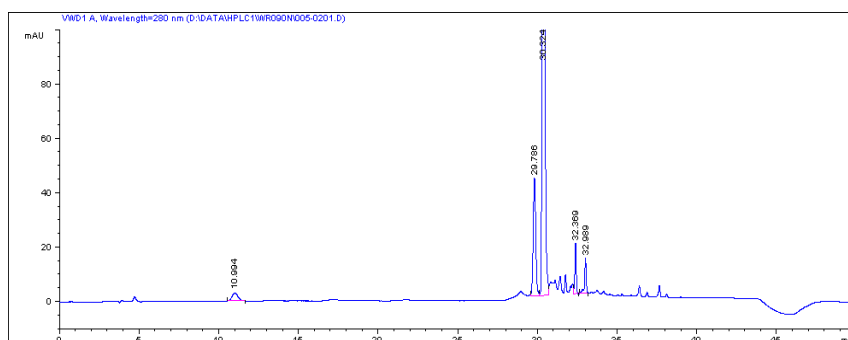
- Column : Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: A: acetonitrile:tetrahydrofuran:triethylamine solution (mix 6 mL of triethylamine and 2000 mL of water, adjust pH to 3.2 with phosphoric acid) = 3:1:96; B: acetonitrile:tetrahydrofuran:triethylamine solution = 29:1:70.  
Gradient: 0 min, 100 %A; 23min, 100 %A; 38min, 0 %A; 40 min, 0 %A; 41 min, 100 %A; 50 min, 100 %A
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR090\004-0301



The chromatogram of the test solution --- HPLC1\WR090\ 005-0201

Constituents (reference solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T,
Impurity	29.79	489.9	173630	/	1.07
Norvancomycin Hydrochloride	30.32	4043.2	257164	2.0	1.47

# Ticlopidine Hydrochloride – 盐酸噻氯匹定

Ticlopidine hydrochloride (100542-200301) – Method number WA185

## Assay

Test solution: Dissolve a quantity of the substance in mobile phase and dilute to produce the test solution of 0.3 mg/mL.

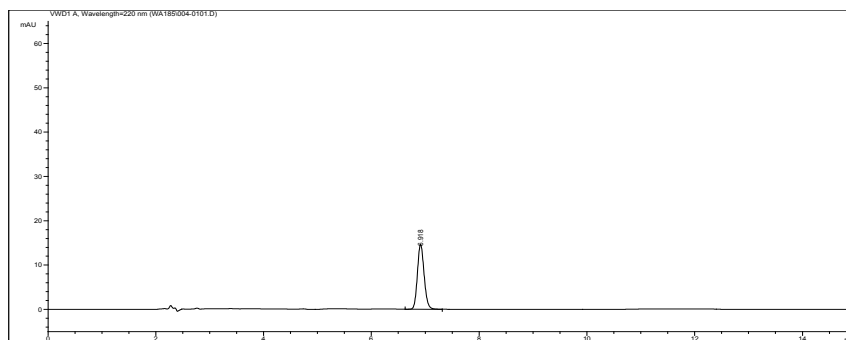
Reference solution: Accurately measure a quantity of the test solution and dilute with mobile phase to produce the reference solution of 3 µg/mL.

## Chromatographic conditions

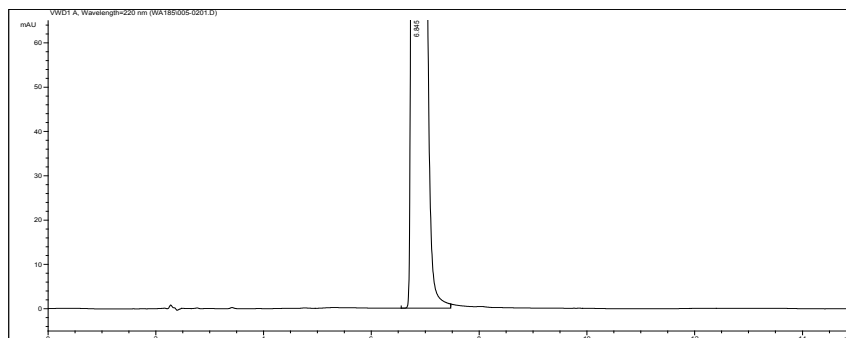
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.022 % sodium pentane sulfonate solution (pH 3.5) : 0.05 M potassium dihydrogen phosphate : methanol : acetonitrile = 11:46:25:18
- Flow rate: 1.0 mL/min Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WA185004-0101



The chromatogram of the test solution--- HPLC1WA185005-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ticlopidine Hydrochloride	6.85	12730.3	10433	/	1.36

# Ticlopidine Hydrochloride Tablets – 盐酸噻氯匹定片

Ticlopidine hydrochloride (100542-200301) – Method number WA186

## Assay

Test solution: Accurately weigh a quantity of the powdered tablets, equivalent to about 30 mg of ticlopidine hydrochloride, in a 100 mL volumetric flask, dissolve and dilute in mobile phase to volume, mix well, filter and use the filtrate as the test solution.

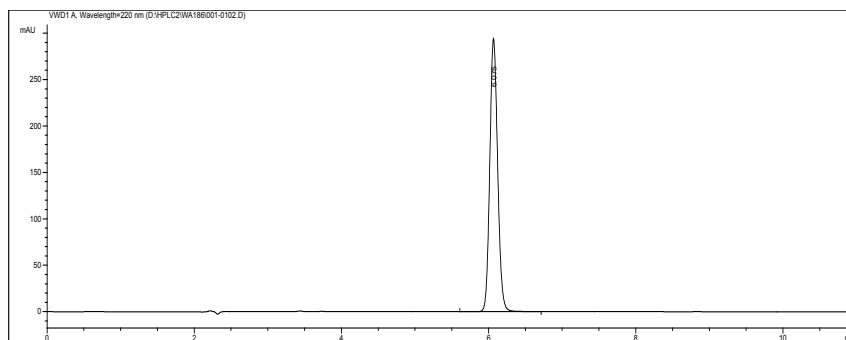
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 0.3 mg/mL.

## Chromatographic conditions

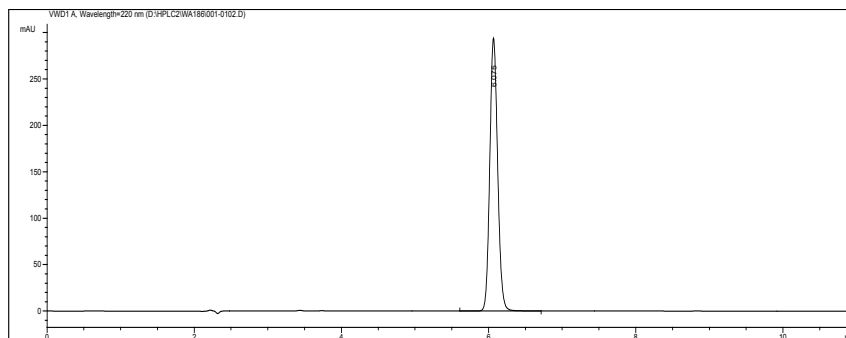
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: 0.022 % sodium pentane sulfonate solution (pH 3.5) : 0.05 M potassium dihydrogen phosphate : methanol: acetonitrile = 11:46:25:18
- Flow rate: 1.0 mL/min
- Injection volume: 20 μL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA186\001-0102



The chromatogram of the test solution--- HPLC2\ WA186\002-0101

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ticlopidine Hydrochloride	6.07	2038.9	12193	/	1.05



# Oxytetracycline Hydrochloride – 盐酸土霉素

Oxytetracycline (130305-200318) – Method number WR089

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in a small volume of 0.1 mol/L hydrochloric acid solution, dilute to 0.15 mg/mL with water, mix well and use as the test solution.

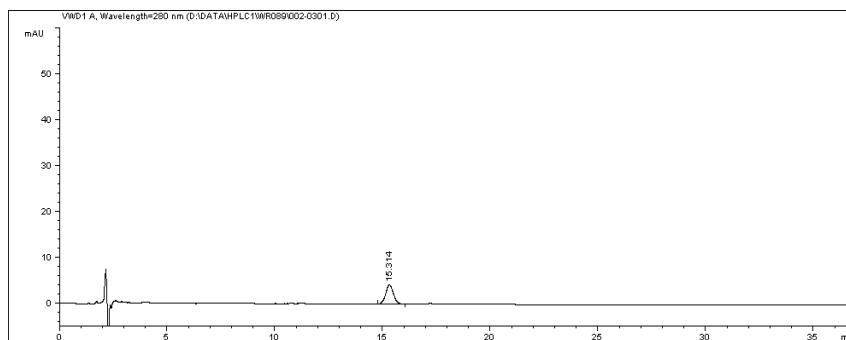
Reference solution: Dissolve a quantity of the substance, dilute to 3 µg/mL with 0.01 mol/L hydrochloric acid solution and use as the reference solution.

## Chromatographic conditions

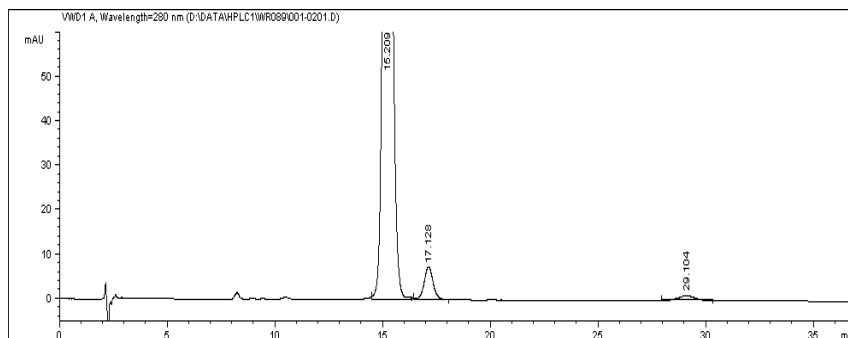
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.05 mol/L ammonium oxalate solution : dimethylformamide : 0.2 mol/L diammonium hydrogen phosphate solution (adjust pH to 8.0 with ammonia TS) = 75: 20:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 35 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR089\002-0301



The chromatogram of the test solution --- HPLC1\WR089\001-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Oxytetracycline	15.21	5516.7	7710	/	1.11
Impurity1	17.13	217.5	8332	2.7	1.02
Impurity2	29.10	56.9	6975	11.2	0.91

# Pseudoephedrine Hydrochloride – 盐酸伪麻黄碱

Ephedrine hydrochloride (171242-200404),

Pseudoephedrine hydrochloride (171237-200304) – Method number WR183

## Assay

Test solution: Dissolve a quantity in mobile phase to produce the test solution of 2 mg/mL.

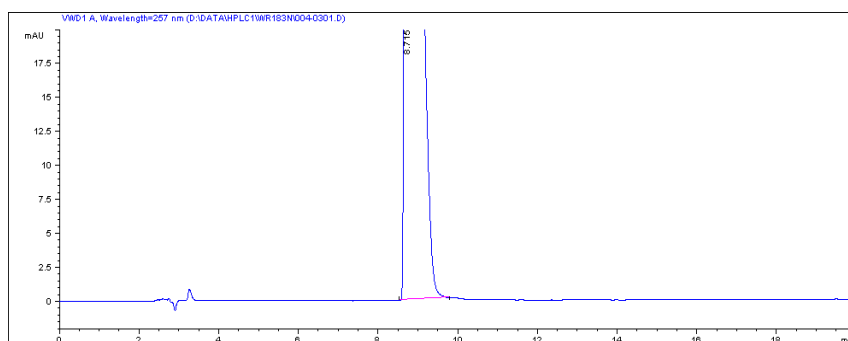
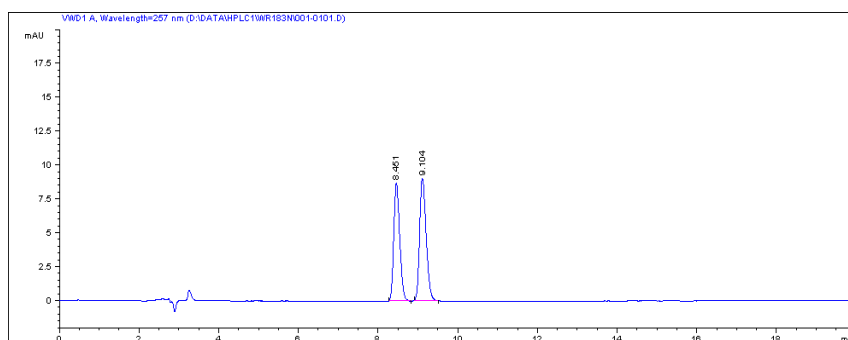
Reference solution: Measure accurately a quantity of the test solution, dilute with mobile phase to produce the reference solution of 10 µg/mL. Dissolve 10 mg of ephedrine hydrochloride CRS in 5 mL of the test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use for the system suitability test.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-Phenyl 4.6×250 mm, 5 µm (880975-912)
- Mobile phase: 1.16 % ammonium acetate solution (adjust pH to 4.0 with acetic acid): methanol = 80:20
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 257 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ephedrine Hydrochloride	8.46	91.1	15148	/	1.14
Pseudoephedrine Hydrochloride	9.12	103.7	14801	2.3	1.18

# Ofloxacin – 氧氟沙星

Ofloxacin (130454-200202) – Method number WR085

## Assay

Test solution: Dissolve an accurately weighed quantity in 0.1 mol/L hydrochloric acid solution to produce the test solution of 1.2 mg/mL.

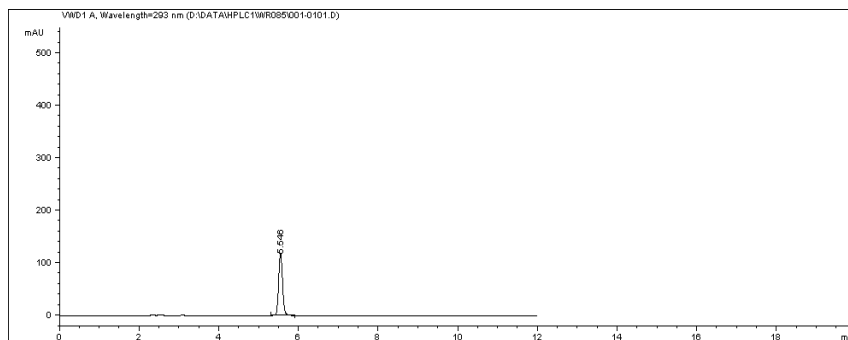
Reference solution: Dissolve a quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid to produce the reference solution of 12 µg/mL.

## Chromatographic conditions

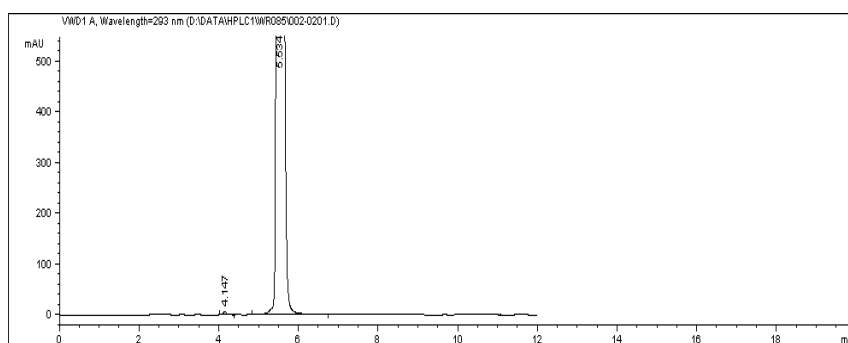
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: ammonium acetate sodium perchlorate solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchlorate in 1300 mL of water, mix well, adjust pH to 2.2 with phosphoric acid): acetonitrile=75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 293 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WA150001-0101.D



The chromatogram of the test solution--- HPLC1\WR085002-0202.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ofloxacin	5.53	29484.3	4859	6.1	1.13
Impurity	4.15	39.0	14328	/	1.18

# Ofloxacin Ear Drops – 氧氟沙星滴耳液

Ofloxacin (130454-200202) – Method number WA150

## Assay

Test solution: Accurately measured a quantity of the drops, equivalent to about 6 mg of ofloxacin, in a 50 mL volumetric flask, dissolve and dilute to volume with a 0.1 mol/L hydrochloric acid solution, mix well and use as the test solution.

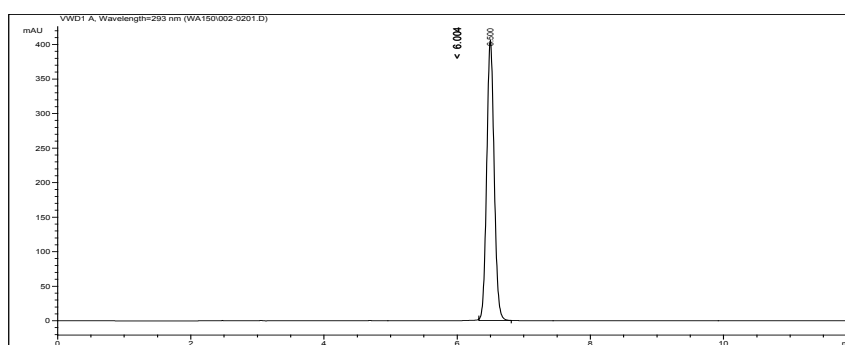
Reference solution: Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 0.12 mg/mL.

## Chromatographic conditions

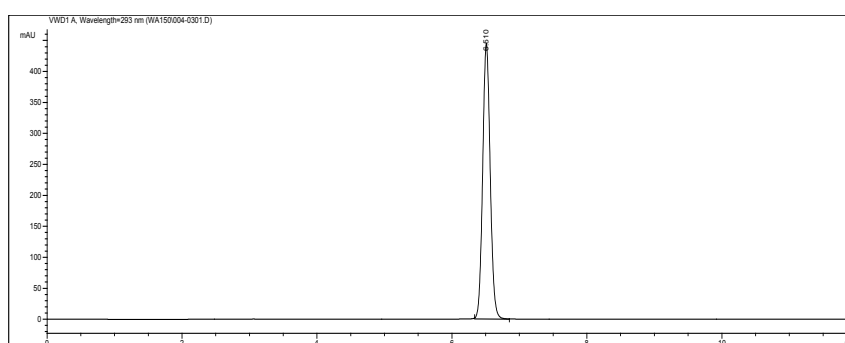
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: ammonium acetate and sodium perchloric solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchloric in 1300 mL of water, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 293 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA150\002-0201



The chromatogram of the test solution--- HPLC1\ WA150\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ofloxacin	6.51	3468.2	16393	/	1.06

# Ofloxacin Eye Drops – 氧氟沙星滴眼液

Ofloxacin (130454-200202) – Method number WA151

## Assay

**Test solution:** Accurately measure 2 mL in a 50 mL volumetric flask, dissolve and dilute to volume with 0.1 mol/L hydrochloric acid solution, mix well, filter and use the filtrate as the test solution.

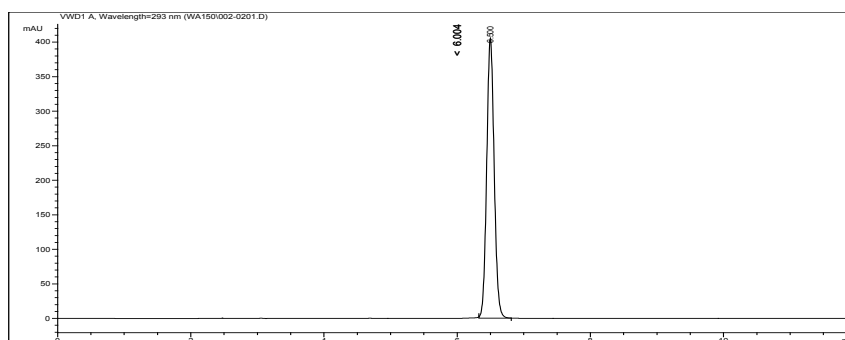
**Reference solution:** Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 0.12 mg/mL.

## Chromatographic conditions

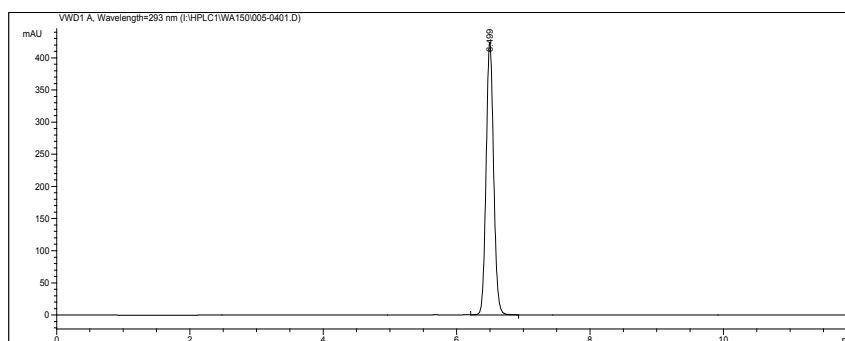
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: ammonium acetate and sodium perchloric solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchloric in 1300 mL of water, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 293 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WA150\002-0201



The chromatogram of the test solution--- HPLC1\ WA150\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ofloxacin	6.50	3325.2	15894	/	1.05

# Ofloxacin Capsules – 氧氟沙星胶囊

## Ofloxacin (130454-200202) – Method number WA148

### Assay

**Test solution:** Accurately weigh a quantity of the well-mixed contents, equivalent to about 0.12 g of ofloxacin, in a 100 mL volumetric flask, dissolve and dilute to volume with 0.1 mol/L hydrochloric acid solution, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute to volume with 0.1 mol/L hydrochloric acid, mix well and use as the test solution.

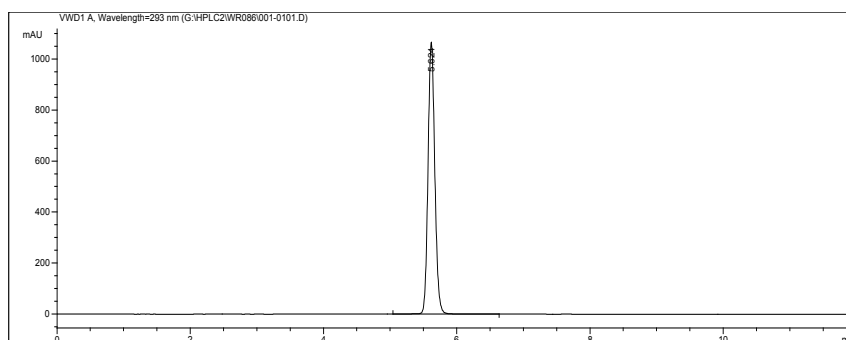
**Reference solution:** Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 0.12 mg/mL.

### Chromatographic conditions

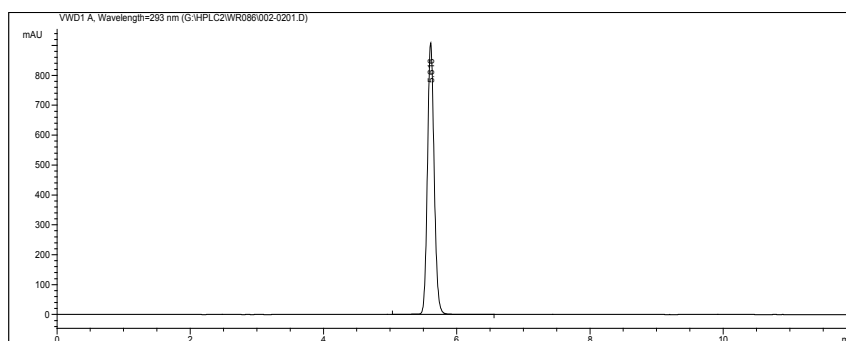
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: ammonium acetate and sodium perchloric solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchloric in 1300 mL of water, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 293 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR086\001-0101



The chromatogram of the test solution --- HPLC2\WR086\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ofloxacin	5.62	6345.8	12529	/	1.06

# Ofloxacin and Sodium Chloride Injection

Ofloxacin (130454-200202) – Method number WR086

氧氟沙星氯化钠注射液

## Assay

**Test solution:** Accurately measure 15 mL in a 25 mL volumetric flask, dilute with 0.1mol/L hydrochloric acid solution to volume, and mix well. Accurately measure 2 ml in a 20 mL volumetric flask, dilute with 0.1mol/L hydrochloric acid solution to volume, mix well and use as the test solution.

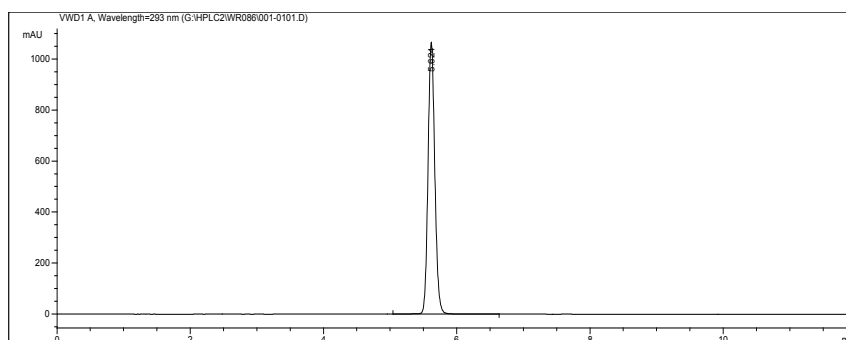
**Reference solution:** Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 0.12 mg/mL.

## Chromatographic conditions

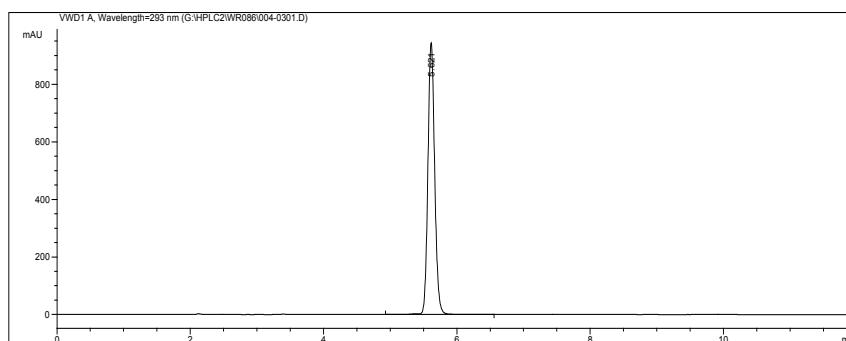
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: ammonium acetate sodium perchlorate solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchlorate in 1300 mL of water, mix well, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 293 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR086001-0101



The chromatogram of the test solution--- HPLC2WR086004-0301

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ofloxacin	5.62	6659.0	13455	/	1.06

# Ofloxacin and Sodium Chloride Injection

Ofloxacin (130454-200202) – Method number WR086

氧氟沙星氯化钠注射液

## Assay

Test solution: Dilute a quantity with 0.1 mol/L hydrochloric acid solution to produce the test solution of 1.2 mg/mL.

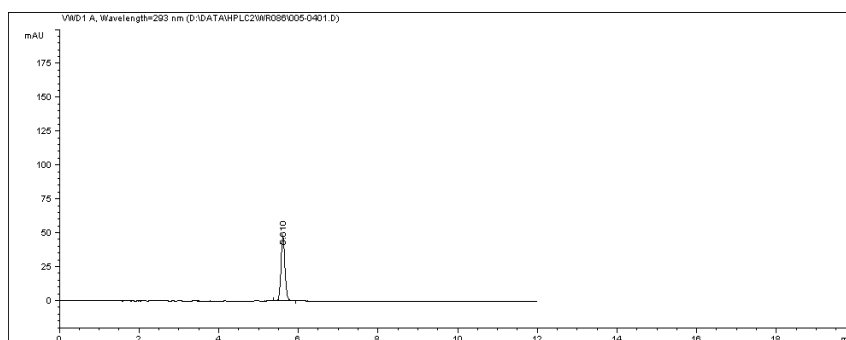
Reference solution: Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 0.12 mg/mL.

## Chromatographic conditions

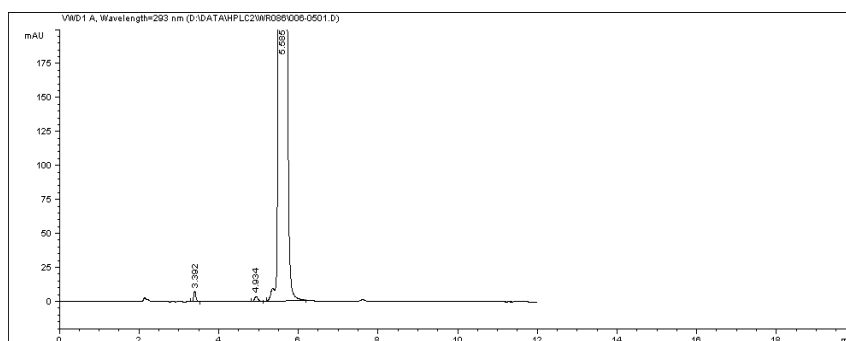
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: ammonium acetate sodium perchlorate solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchlorate in 1300 mL of water, mix well, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 293 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR086005-0401



The chromatogram of the test solution--- HPLC2WR086006-0501

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ofloxacin	5.59	20451.5	7885	3.2	1.16
Impurity1	3.39	31.4	17314	/	1.16
Impurity2	4.93	23.6	15453	11.8	/



# Ofloxacin Tablets – 氧氟沙星片

Ofloxacin (130454-200202) – Method number WR188

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to about 0.12 g of ofloxacin, in a 100 mL volumetric flask, dissolve and dilute to volume with 0.1 mol/L hydrochloric solution, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with 0.1 mol/L hydrochloric solution to volume, mix well and use as the test solution.

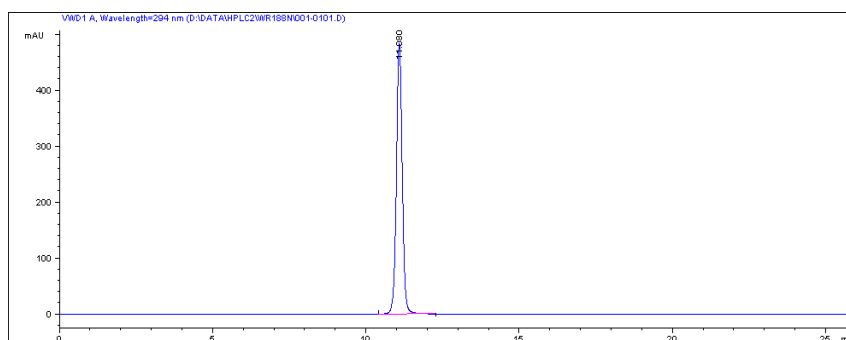
Reference solution: Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 0.12 mg/mL.

## Chromatographic conditions

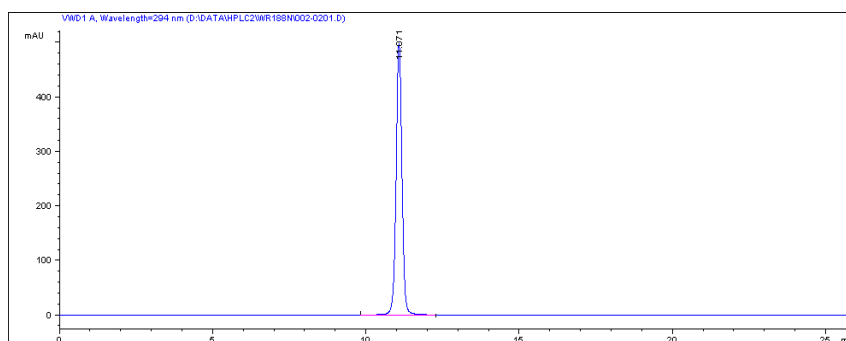
- Column: Agilent ZORBAX SB-Aq, 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: ammonium acetate sodium perchloric solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchloric in 1300 mL of water, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 80:20
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 294 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR188N001-0101



The chromatogram of the test solution --- HPLC2\WR188N002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ofloxacin	11.07	6738.4	18016	/	1.01

# Ofloxacin Tablets – 氧氟沙星片

## Ofloxacin (130454-200202) – Method number WR188

### Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Dissolve an accurately weighed quantity of the powder, equivalent to about 0.12 g of ofloxacin, in a 100 mL volumetric flask, dissolve and dilute to volume with 0.1 mol/L hydrochloric solution, mix well and filter. Accurately measure 5 mL of the filtrate in a 50 mL volumetric flask, dilute with 0.1 mol/L hydrochloric solution to volume, mix well and use as the test solution.

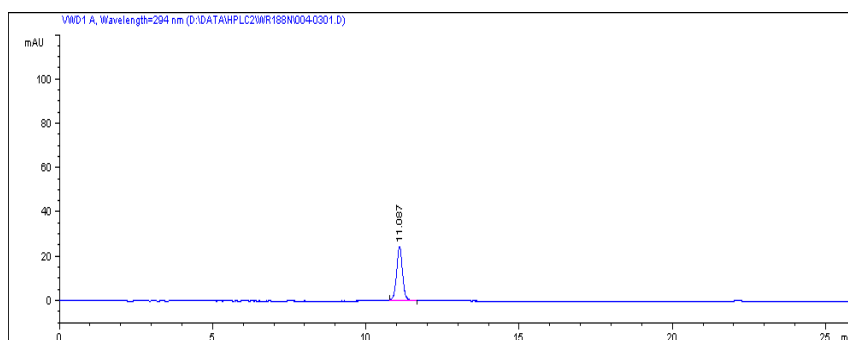
Reference solution: Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 6 µg/mL.

### Chromatographic conditions

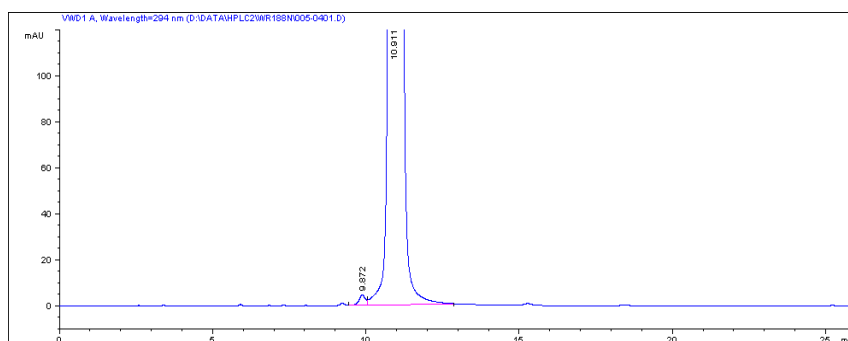
- Column: Agilent ZORBAX SB-Aq, 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: ammonium acetate sodium perchloric solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchloric in 1300 mL of water, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 80:20
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 294 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2\WR188\N004-0301.D



The chromatogram of the test solution--- HPLC2\WR188\N005-0402.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ofloxacin	10.91	43548.3	7054	2.1	1.24
Impurity	9.87	71.5	7223	/	/

# Ofloxacin Eye Ointment – 氧氟沙星眼膏

Ofloxacin (130454-200202) – Method number WA149

## Assay

Test solution: Dissolve an accurately weighed quantity of about 2 g of the ointment in 40 mL petroleum ether (60-90 °C), shake well, extract using three 15 mL quantities of 0.1 mol/L hydrochloric acid in a 50 mL volumetric flask, dilute to volume with 0.1 mol/L hydrochloric acid solution, mix well and use as the test solution.

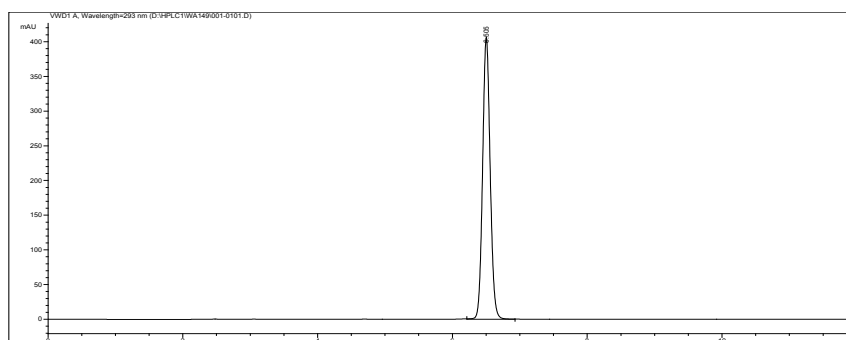
Reference solution: Dissolve an accurately weighed quantity of ofloxacin CRS in 0.1 mol/L hydrochloric acid solution to produce the reference solution of 0.12 mg/mL.

## Chromatographic conditions

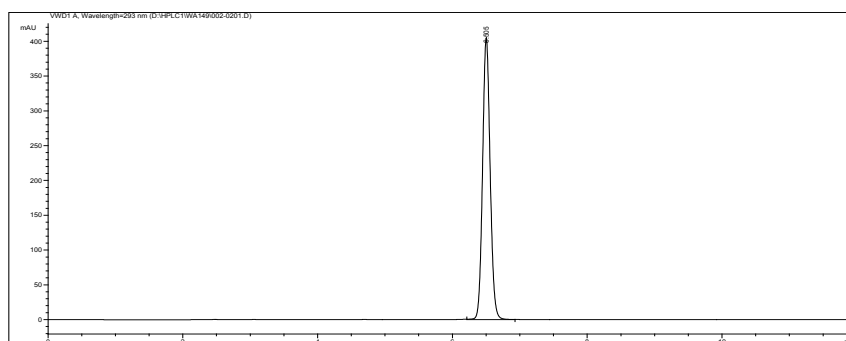
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: ammonium acetate and sodium perchloric solution (dissolve 4.0 g of ammonium acetate and 7.0 g of sodium perchloric in 1300 mL of water, adjust pH to 2.2 with phosphoric acid) : acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 293 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA149\001-0101



The chromatogram of the test solution --- HPLC1\WA149\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ofloxacin	6.51	3166.1	16356	/	1.06

# Enoxacin – 依诺沙星

Enoxacin (0452-9901) – Method number WR054

## Assay

Test solution: Accurately weigh about 50 mg of the substance in a 100 mL volumetric flask, dissolve in 20 mL of 0.1 mol/L hydrochloric acid solution, dilute with mobile phase to volume, mix well and use as the test solution.

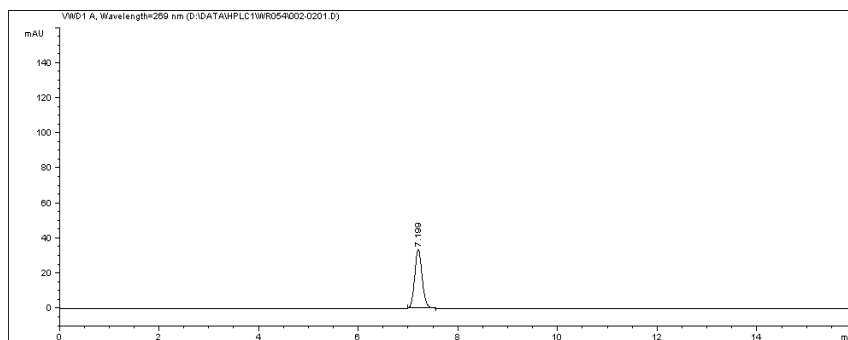
Reference solution: Accurately measure a quantity and dilute with mobile phase to produce the reference solution of 5 µg of enoxacin per mL.

## Chromatographic conditions

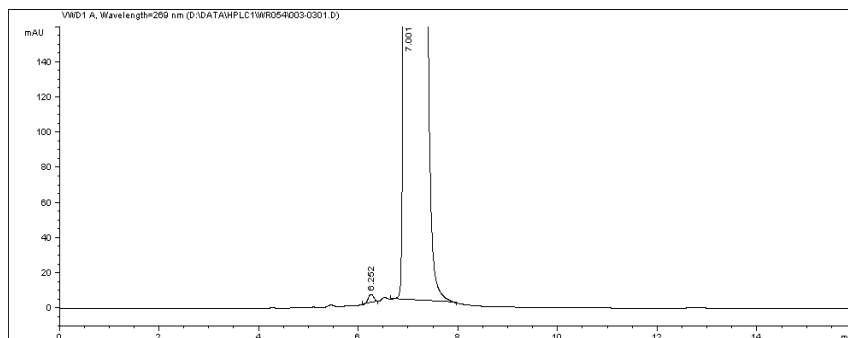
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: 0.025 mol/L phosphoric acid solution (adjust pH to 3.0 with triethylamine) : methanol : acetonitrile = 84:8:8
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 269 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR054\002-0201



The chromatogram of the test solution --- HPLC1\WR054\003-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Enoxacin	7.00	59354.5	3257	2.1	/
Impurity	6.25	328.9	13599	/	1.18

# Enoxacin Eye Drops – 依诺沙星滴眼液

Enoxacin (0452-9901) – Method number WA093

## Assay

Test solution: Dilute an accurately measured quantity of drops with mobile phase to produce a solution of 10 µg of enoxacin per mL, shake well and use as the test solution.

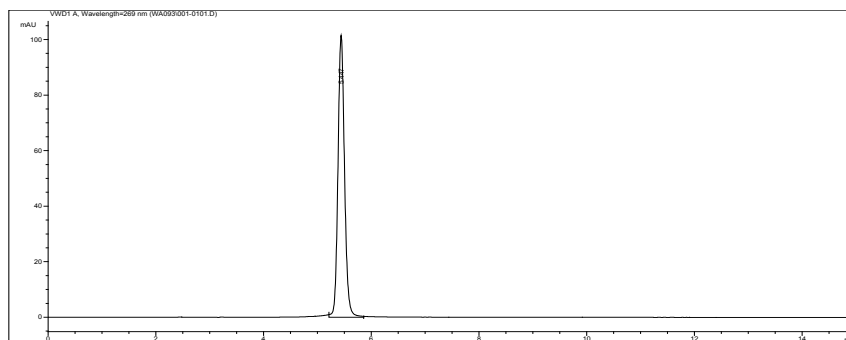
Reference solution: Repeat the procedure using an accurately weighed quantity of enoxacin CRS to produce the reference solution.

## Chromatographic conditions

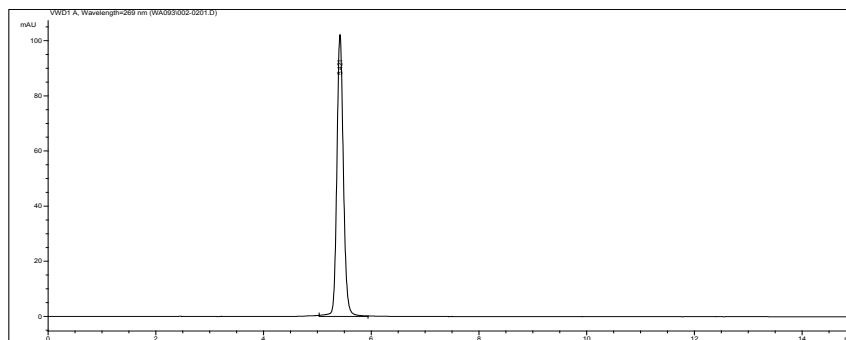
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: 0.025 mol/L phosphoric acid solution (adjust to pH 3.0 with triethylamine): methanol : acetonitrile = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 269 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WA093\001-0101



The chromatogram of the test solution --- HPLC2\WA093\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Enoxacin	5.42	856.7	10233	/	1.10

# Enoxacin Capsules – 依诺沙星胶囊

Enoxacin (0452-9901) – Method number WR056

## Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of enoxacin, in a 100 mL volumetric flask, add 20 mL of 0.1 mol/L hydrochloric acid solution to dissolve the enoxacin, dilute with mobile phase to volume, mix well and filter. Accurately measure 2 mL of the filtrate in a 100 mL volumetric flask, dilute with mobile phase to volume and use as the test solution.

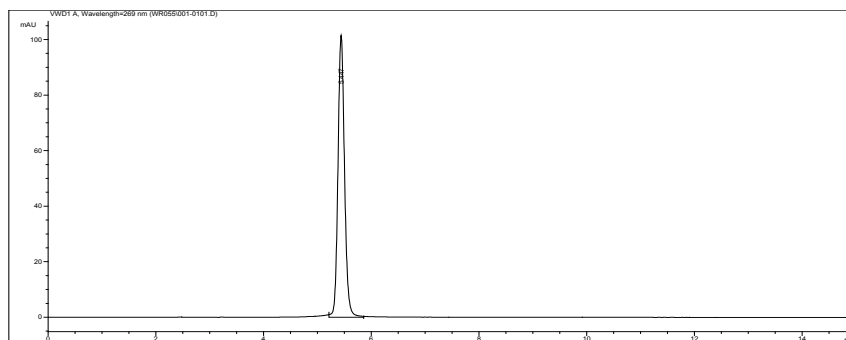
Reference solution: Produce the reference solution using enoxacin CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

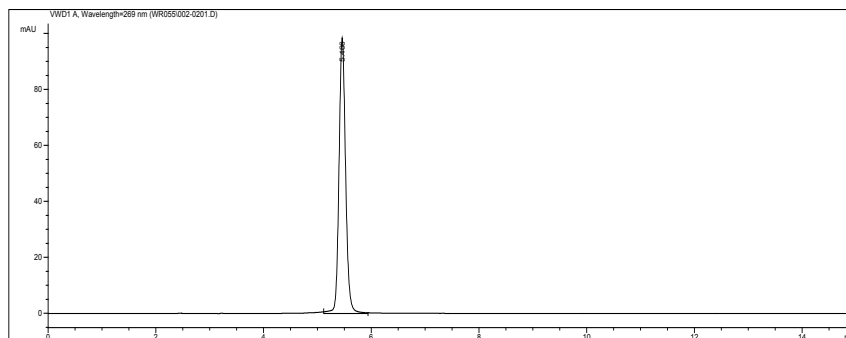
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: 0.025 mol/L phosphoric acid solution (adjust to pH 3.0 with triethylamine) : methanol : acetonitrile = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 269 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR056\001-0101



The chromatogram of the test solution--- HPLC2WR056\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Enoxacin	5.41	841.6	9097	/	1.09

# Enoxacin Tablets – 依诺沙星片

Enoxacin (0452-9901) – Method number WR055

## Assay

Test solution: Accurately weigh 10 tablets and grind to a fine powder. Accurately weigh a quantity of the powder, equivalent to about 50 mg of enoxacin, in a 100 mL volumetric flask, add 20 mL of 0.1 mol/L hydrochloric acid solution to dissolve the enoxacin, dilute with mobile phase to volume, mix well and filter. Accurately measure 2 mL of the filtrate in a 50 mL volumetric flask, dilute with mobile phase to volume and use as the test solution.

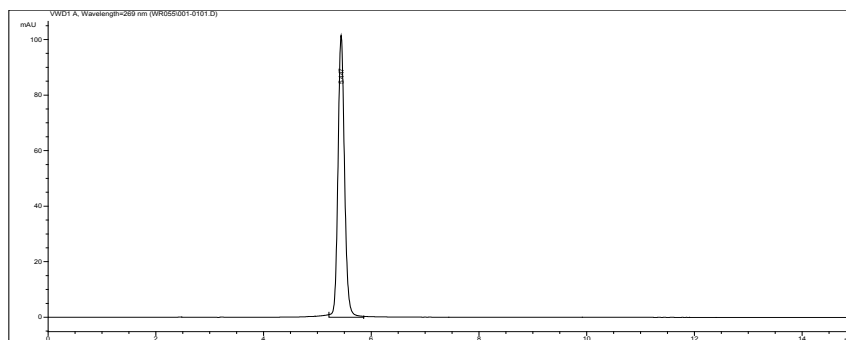
Reference solution: Produce the reference solution using enoxacin CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

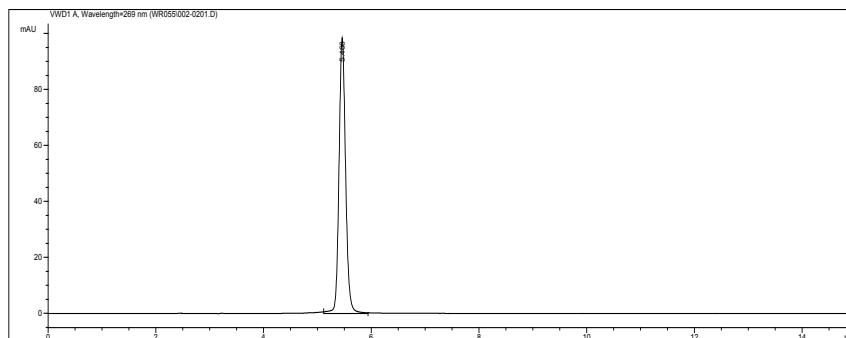
- Column: Agilent ZORBAX Bonus-RP 4.6×250 mm, 5 µm (880668-901)
- Mobile phase: 0.025 mol/L phosphoric acid solution (adjust to pH 3.0 with triethylamine) : methanol : acetonitrile = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 269 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR055\001-0101



The chromatogram of the test solution --- HPLC2\WR055\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Enoxacin	5.46	838.5	8963	/	1.08

# Etoposide – 依托泊昔

## Etoposide (ARCOS) – Method number WA090

### Assay

Test solution: Dissolve an accurately weighed quantity of the substance in a mixture of acetonitrile and 0.02 mol/L sodium acetate BS (30:70, pH 4.0) to produce the test solution of 2 mg/mL.

Reference solution: Dissolve an accurately weighed quantity of etoposide CRS with acetonitrile to produce a solution of 2 mg/mL. Accurately measure 1 mL of this solution in a 200 mL volumetric flask, dilute with a mixture of acetonitrile and 0.02 mol/L sodium acetate BS (30:70, pH 4.0) to volume, mix well and use as the reference solution.

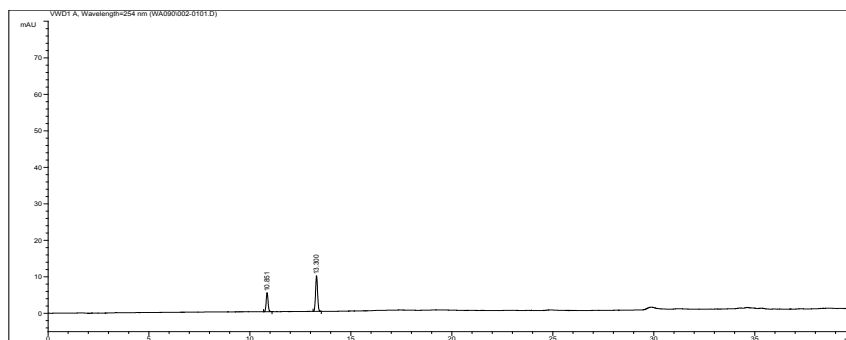
- Mobile phase:  
A: acetonitrile : acetate BS  
(dissolve 2.72 g of sodium acetate with 2000 mL of water, adjust pH to 4.0 with glacial acetic acid) (20:80)  
B: acetonitrile:acetate BS (60:40)  
Gradient: 0-15 min, 0 %B;  
30-40 min, 60 %B;  
42-45 min, 100 %B;  
47-50 min, 0 B%.

### Chromatographic conditions

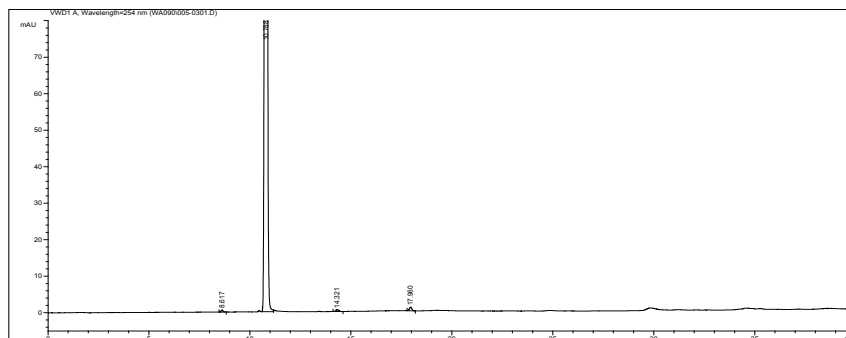
- Column: Agilent ZORBAX SB-Phenyl 4.6×250 mm, 5 µm (880975-912)
- Mobile phase: see assay
- Flow rate: 1.5 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability --- HPLC1\WA090\002-0101



The chromatogram of the test solution --- HPLC1\WA090\005-0301

Constituents (system suitability)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Etoposide	10.85	33.8	65886	/	1.05
Propyl 4-Hydroxybezoate	13.30	68.1	85941	14.0	1.05



# Etoposide Injection – 依托泊昔注射液

Etoposide (ARCOS) – Method number WA091

## Assay

Test solution: Accurately measure 5 mL in a 100 mL volumetric flask, dilute with mobile phase to volume and mix well. Accurately measure 10 ml of this solution in a 50 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the test solution.

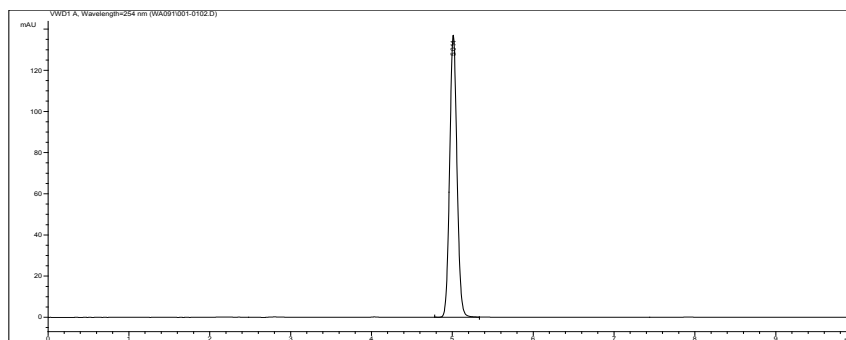
Reference solution: Dissolve an accurately weighed quantity of etoposide CRS dried in vacuum at 80 °C for 6 hours with mobile phase to produce the reference solution of 0.2 mg/mL.

## Chromatographic conditions

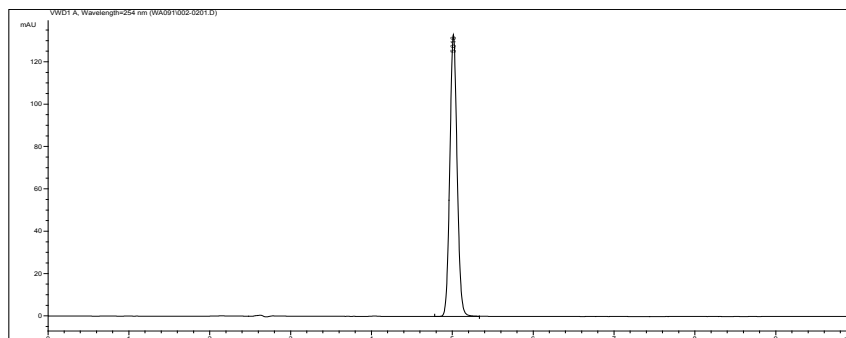
- Column: Agilent ZORBAX SB-Phenyl 4.6×250 mm, 5 µm (880975-912)
- Mobile phase: acetonitrile : 0.02 mol/L sodium acetate (adjust pH to 4.0 with glacial acetic acid) = 40:60
- Flow rate: 1.5 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA091\001-0102



The chromatogram of the test solution --- HPLC1\ WA091\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Etoposide	5.02	832.8	13744	/	1.05

# Indometacin – 吲哚美辛

Indometacin (100258-199602) – Method number WR042

## Assay

Test solution: Accurately weigh a quantity, equivalent to about 50 mg of indometacin, in a 100 mL volumetric flask, add a quantity of 50 % ethanol, treat ultrasonically to dissolve the indometacin, dilute with 50 % ethanol to volume and mix well. Accurately measure 5 mL in a 25 mL volumetric flask, dilute with 50 % ethanol to volume, mix well and use as the test solution.

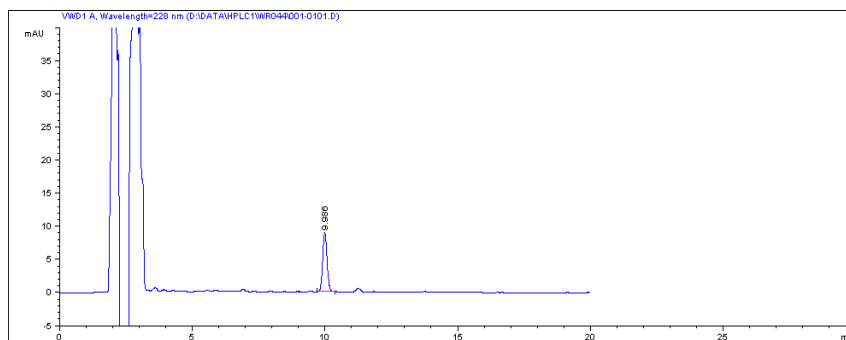
Reference solution: Accurately measure 1 mL of the test solution in a 200 mL volumetric flask and dilute with 50 % ethanol to volume to produce the reference solution.

## Chromatographic conditions

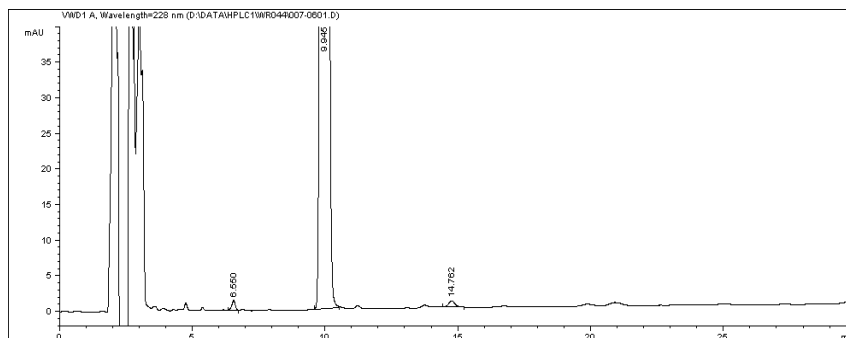
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: 0.1 M acetic acid: acetonitrile = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 50 μL
- Column temperature: 30 °C
- Detector wavelength: 228 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR044\001-0101.D



The chromatogram of the test solution--- HPLC1\WR044\007-0601.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Indometacin	9.95	17954.4	17950	12.6	1.08
Impurity1	6.55	13.2	11997	/	0.90
Impurity2	14.76	14.6	19704	13.4	1.05

# Indometacin Capsules – 吲哚美辛胶囊

## Indometacin (100258-199602) – Method number WR044

### Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of indometacin, in a 100 mL volumetric flask, add a quantity of 50% ethanol, treat ultrasonically to dissolve the indometacin, dilute with 50% ethanol to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with 50 % ethanol to volume, mix well and use as the test solution.

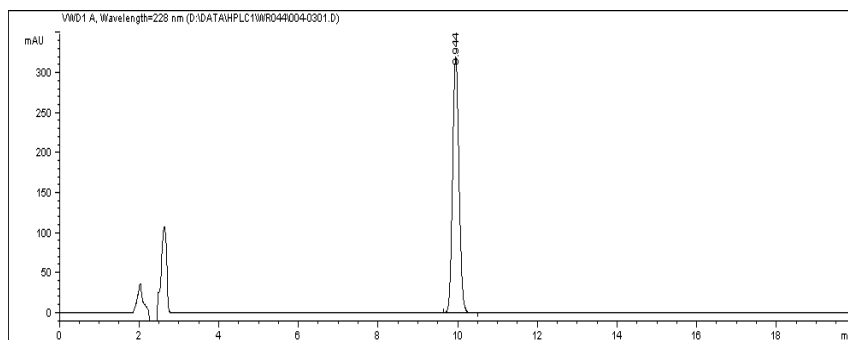
Reference solution: Repeat the procedure using indometacin CRS to produce the reference solution.

### Chromatographic conditions

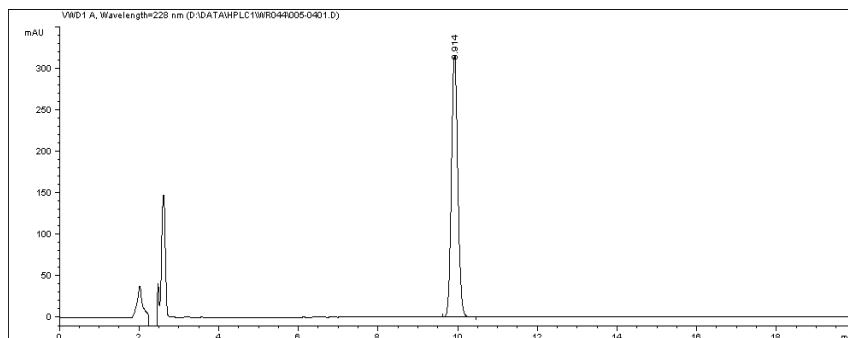
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: 0.1M acetic acid: acetonitrile = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 228 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR044\004-0301.D



The chromatogram of the test solution--- HPLC1\WR044\005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Indometacin	9.91	3503.7	18345	/	1.06

# Indometacin Capsules – 吲哚美辛胶囊

## Indometacin (100258-199602) – Method number WR044

### Assay

Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 50 mg of indometacin, in a 100 mL volumetric flask, add a quantity of 50 % ethanol, treat ultrasonically to dissolve the indometacin, dilute with 50 % ethanol to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with 50 % ethanol to volume, mix well and use as the test solution.

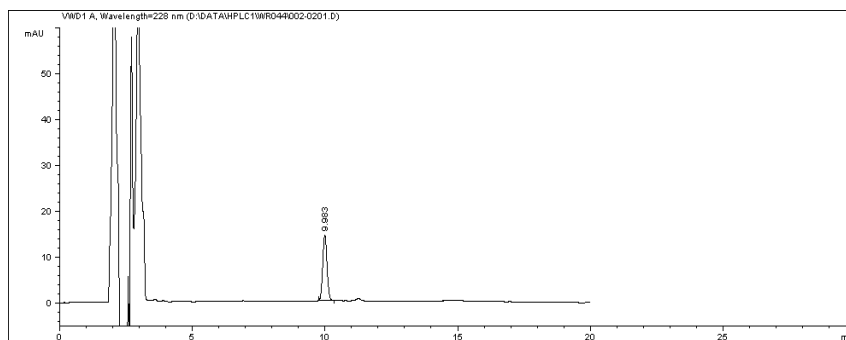
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with 50 % ethanol to volume and use as the reference solution.

### Chromatographic conditions

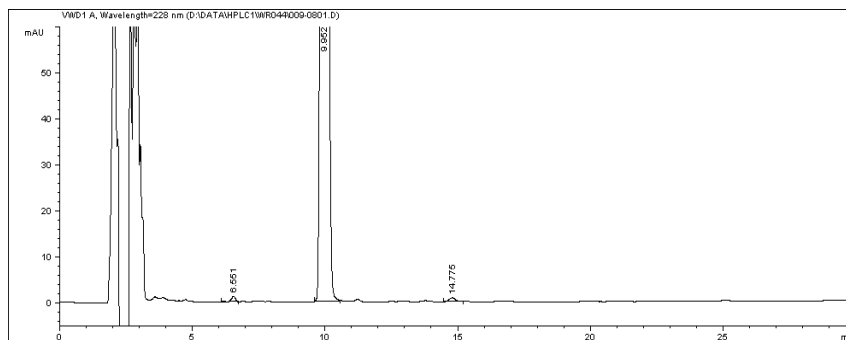
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: 0.1 M acetic acid: acetonitrile = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 228 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR044\002-0201.D



The chromatogram of the test solution--- HPLC1\WR044\009-0801.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Indometacin	9.95	17569.1	17976	12.3	1.10
Impurity1	6.55	12.9	10503	/	0.89
Impurity2	14.78	15.6	18278	13.1	/

# Indometacin Suppositories – 吲哚美辛栓

Indometacin (100258-199602) – Method number WR043

## Assay

Test solution: Accurately weigh 10 suppositories, cut carefully into pieces and mix well. Accurately weigh a quantity, equivalent to about 25 mg of indometacin, in a 50 mL volumetric flask, add a quantity of 50 % ethanol, heat on a water bath and treat ultrasonic to dissolve the indometacin, allow to cool to room temperature, dilute with 50 % ethanol to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with 50 % ethanol to volume, mix well and use as the test solution.

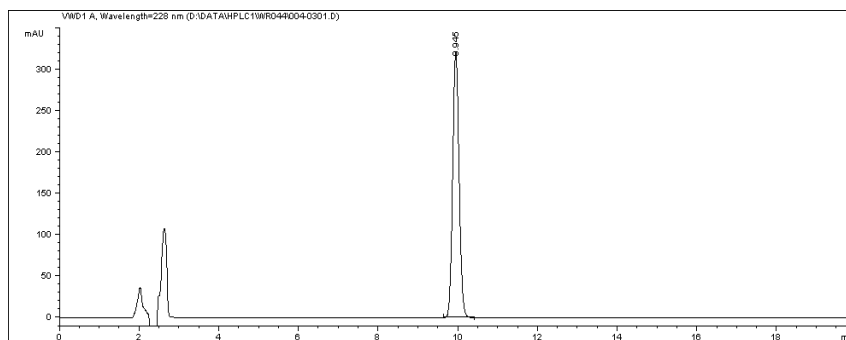
Reference solution: Repeat the procedure using indometacin CRS to produce the reference solution.

## Chromatographic conditions

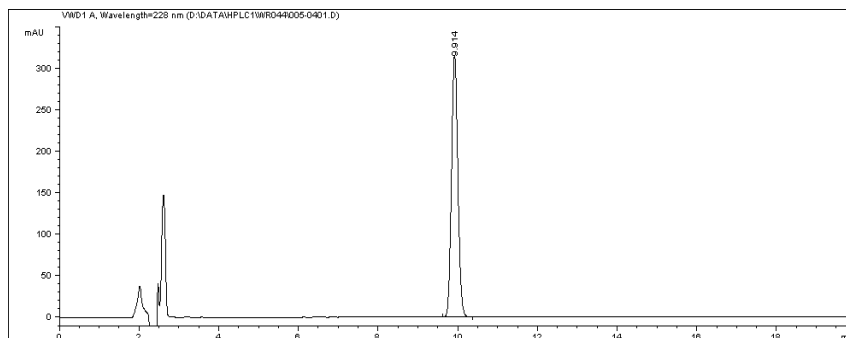
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.1 M acetic acid: acetonitrile = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 228 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR044\004-0301.D



The chromatogram of the test solution--- HPLC1\WR044\005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Indometacin	9.92	3503.5	17354	/	1.06

# Indometacin Suppositories – 吲哚美辛栓

## Indometacin (100258-199602) – Method number WR043

### Assay

Test solution: Accurately weigh 10 suppositories, cut carefully into pieces and mix well. Accurately weigh a quantity, equivalent to about 25 mg of indometacin, in a 50 mL volumetric flask, add a quantity of 50 % ethanol, heat on a water bath and treat ultrasonic to dissolve the indometacin, allow to cool to room temperature, dilute with 50 % ethanol to volume, mix well and filter. Accurately measure 5 mL of the filtrate in a 25 mL volumetric flask, dilute with 50 % ethanol to volume, mix well and use as the test solution.

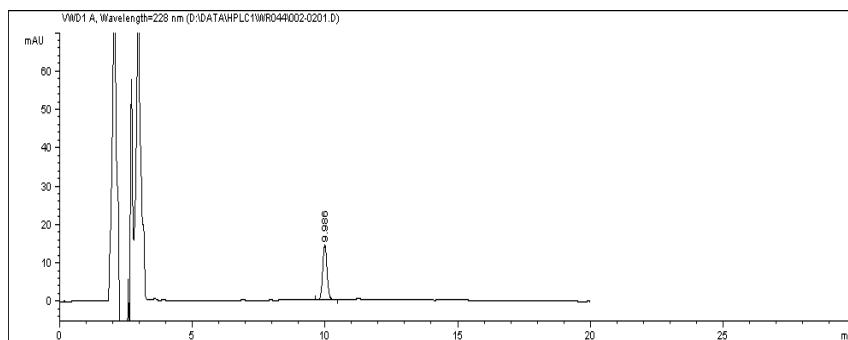
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with 50 % ethanol to volume and use as the reference solution.

### Chromatographic conditions

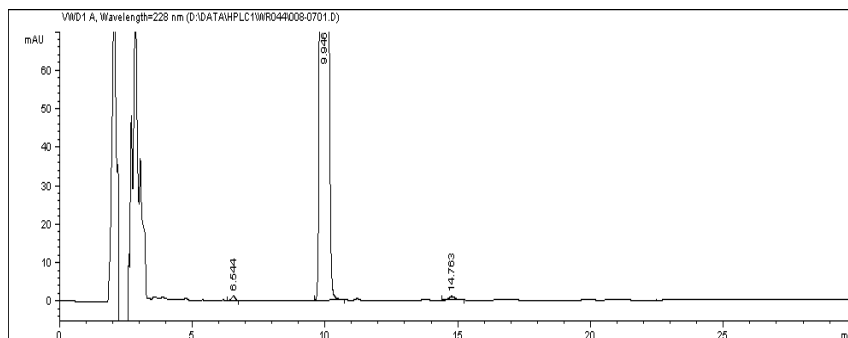
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: 0.1 M acetic acid: acetonitrile = 45:55
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 228 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC1\WR044\002-0201.D



The chromatogram of the test solution--- HPLC1\WR044\008-0701.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Indometacin	9.95	17513.7	17463	12.4	1.08
Impurity1	6.54	13.1	11446	/	0.90
Impurity2	14.76	17.8	17908	12.9	1.49

# Amoxicillin Sodium and Clavulanate Potassium for Injection

Amoxicillin (130409-200208), Clavulanic acid (130429-200203) – Method number WR059  
注射用阿莫西林钠克拉维

## Assay

Test solution: Dissolve an accurately weighed quantity of the contents in water to produce the test solution of 0.5 mg amoxicillin and 0.1 mg clavulanic acid per mL.

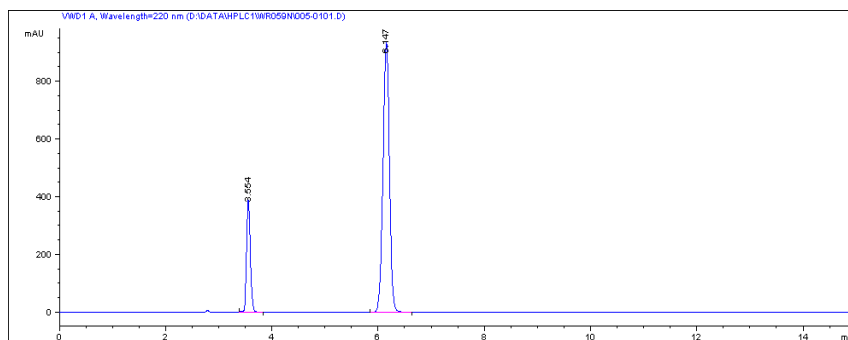
Reference solution: Dissolve a quantity of amoxicillin CRS and clavulanic acid CRS in water to produce the reference solution of 0.5 mg amoxicillin and 0.1 mg clavulanic acid per mL.

## Chromatographic conditions

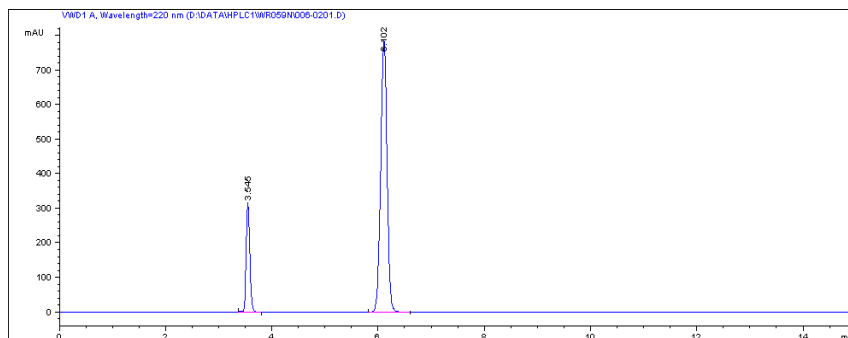
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.01 mol/L potassium dihydrogen phosphate (pH 6.0) : acetonitrile = 96:4
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR059N005-0101



The chromatogram of the test solution --- HPLC1\WR059N006-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clavulanic acid	3.55	1542.2	12793	/	1.12
Amoxicillin	6.10	6598.8	12014	14.7	1.01

# Amoxicillin Sodium and Clavulanate Potassium for Injection

Amoxicillin (130409-200208) – Method number WR059

注射用阿莫西林钠克拉维酸钾

## Assay

Test solution: Dissolve an accurately weighed quantity of the contents in mobile phase to produce a solution of 2 mg of amoxicillin per mL, filter and use the filtrate as the test solution.

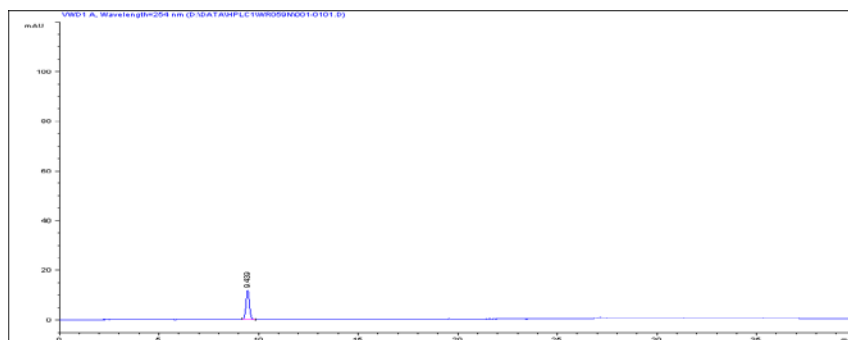
Reference solution: Dissolve a quantity of amoxicillin CRS in mobile phase to produce the reference solution of 40 µg/mL.

## Chromatographic conditions

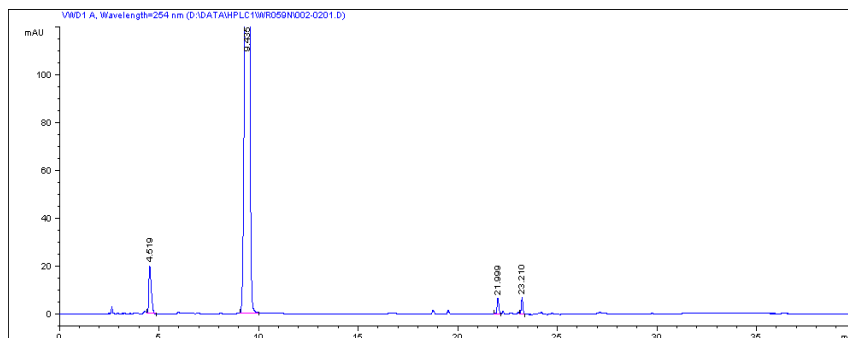
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: A: 0.01 mol/L potassium dihydrogen phosphate (pH=6.0); B: acetonitrile-A (80:20) Gradient: 0 min, 0 %B; 1 min, 2 %B; 9 min, 2 %B; 30.5 min, 41 %B; 32 min, 2 %B; 35 min, 0 %B; 40 min, 0 %B
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR059N\001-0101.D



The chromatogram of the test solution --- HPLC2\WR059N\002-0201.D

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Clavulanic acid	4.52	171.7	6588	/	1.63
Amoxicillin	9.44	5360.7	12157	17.4	0.86



# Amoxicillin Sodium for Injection – 注射用阿莫西林钠

Amoxicillin (130409-200208) – Method number WR164

## Assay

Test solution: Dissolve a quantity of the contents in mobile phase and dilute to produce the test solution containing 0.5 mg/mL.

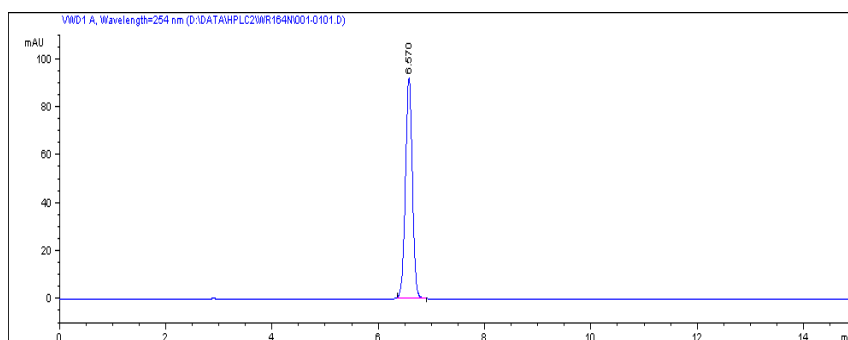
Reference solution: Dissolve a quantity of amoxicillin CRS in mobile phase and dilute to produce the reference solution containing 0.5 mg/mL.

## Chromatographic conditions

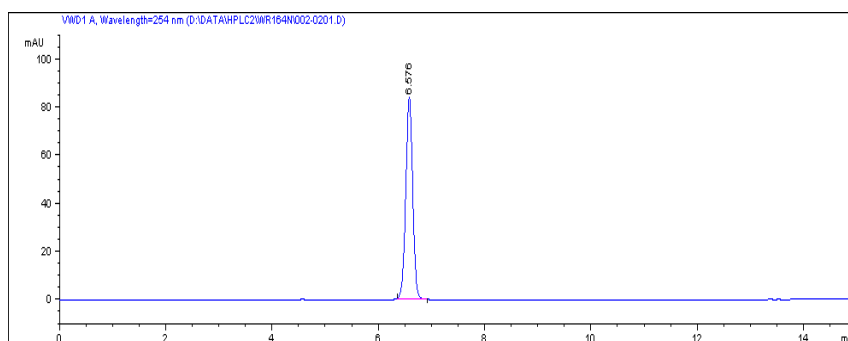
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.05 mol/L potassium dihydrogen phosphate solution (adjust pH to 5.0 with 2 mol/L sodium hydroxide solution) : acetonitrile = 97.5:2.5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2\WR164N\001-0101



The chromatogram of the test solution --- HPLC2\WR164N\002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Amoxicillin	6.58	768.1	12378	/	0.99

# Aciclovir for Injection – 注射用阿昔洛韦

Aciclovir (140630-200001) – Method number WA269

## Assay

Test solution: Accurately weigh a quantity of the powder, equivalent to about 50 mg of acyclovir, in a 250 mL volumetric flask, dissolve and dilute with water to volume, mix well and filter. Dilute an accurately measured quantity of the filtrate with water and mix well to produce the test solution of 20 µg of aciclovir per mL.

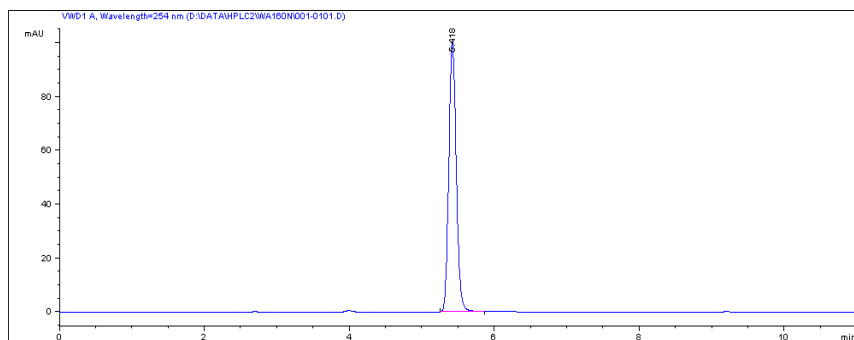
Reference solution: repeat the procedure using aciclovir CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

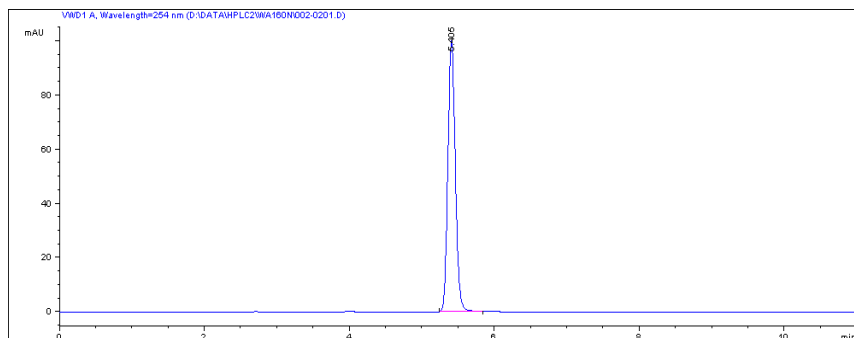
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : water = 10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA081\001-0101



The chromatogram of the test solution--- HPLC2\ WA081\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Aciclovir	5.41	717.6	14197	/	1.09

# Aciclovir for Injection – 注射用阿昔洛韦

Aciclovir (140630-200001) –Method number WA269

## Assay

Test solution: Accurately weigh a quantity of the powder, equivalent to about 50 mg of acyclovir, in a 250 mL volumetric flask, dissolve and dilute with water to volume, mix well and filter. Dilute an accurately measured quantity of the filtrate with water to produce a solution of 20 µg of aciclovir per mL, mix well and use as the test solution.

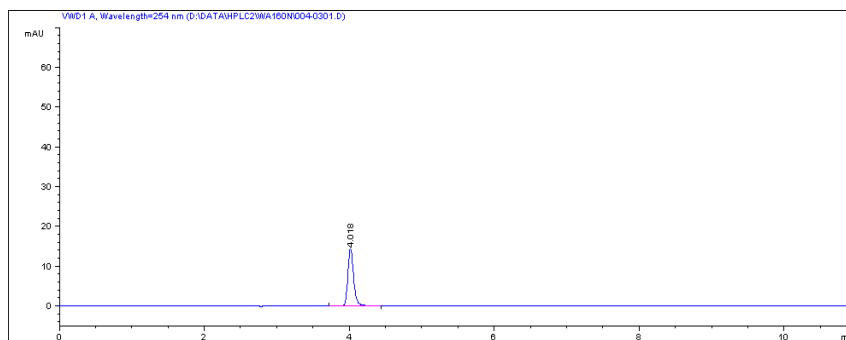
Reference solution: Dissolve 10 mg of guanine CRS in 0.4 % sodium hydroxide solution in a 100 mL volumetric flask, dilute to volume and mix well. Accurately measure 2 mL in a 100 mL volumetric flask, dilute with water to volume, mix well and use as the reference solution.

## Chromatographic conditions

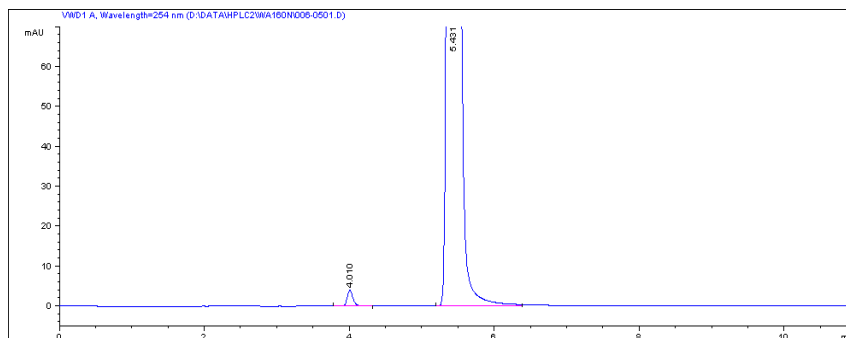
- Column: Agilent ZORBAX SB C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : water = 10:90
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA081\001-0101



The chromatogram of the test solution--- HPLC2\ WA081\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Guanine	4.01	21.9	11671	/	1.16
Aciclovir	5.43	7092.9	13702	8.5	1.09

# Ampicillin Sodium for Injection – 注射用氨苄西林钠

Ampicillin (0410-200004) – Method number WR191

## Assay

Test solution: Accurately weigh about 30 mg of the contents and dissolve in mobile phase to produce the test solution of 0.3 mg/mL.

Reference solution: Repeat the procedure using ampicillin CRS to produce the reference solution.

### • Mobile phase:

A: 12 % acetic acid solution : 0.2 mol/L potassium dihydrogen phosphate solution : acetonitrile : water (0.5:50:50:900)

B: 12 % acetic acid solution : 0.2 mol/L potassium dihydrogen phosphate solution : acetonitrile : water (0.5:50:400:550)

Gradient: 0 min: 85 %A:

10 min, 85 %A; 40 min, 0 %A;

50 min, 0 %A; 51 min, 85 %A;

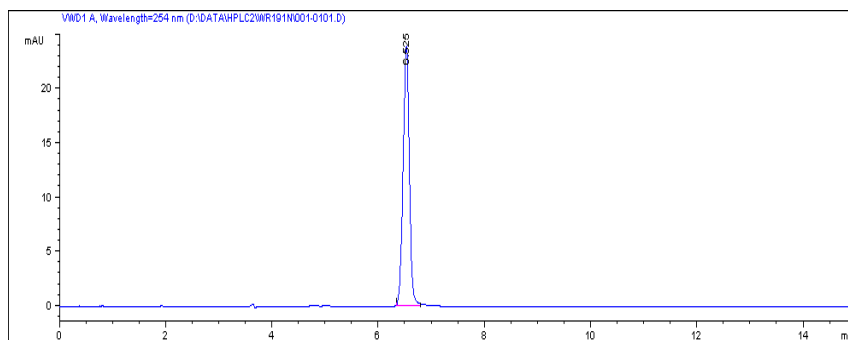
60 min, 85 %A

## Chromatographic conditions

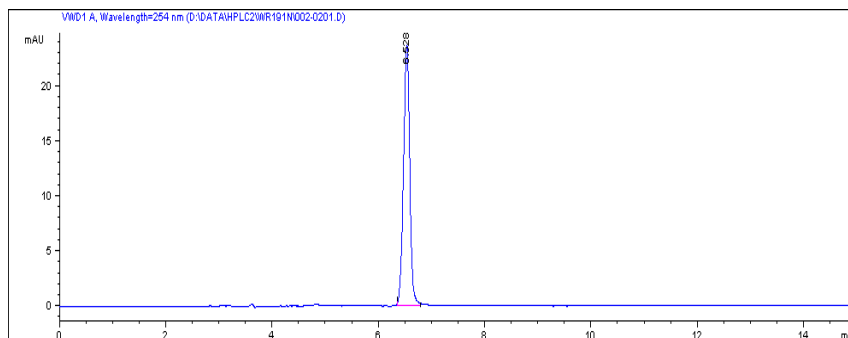
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: see assay
- Flow rate: 1 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR191N001-0101.D



The chromatogram of the test solution--- HPLC2WR191N002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ampicillin	6.53	195.8	15215	/	1.00

# Ampicillin Sodium for Injection – 注射用氨苄西林钠

Ampicillin (0410-200004) – Method number WR191

## Assay

Test solution: Accurately weigh about 30 mg of the contents and dissolve in mobile phase to produce the test solution of 0.3 mg/mL.

Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with mobile phase to volume, mix well and use as the reference solution.

### • Mobile phase:

A: 12 % acetic acid solution : 0.2 mol/L potassium dihydrogen phosphate solution : acetonitrile : water (0.5:50:50:900)

B: 12 % acetic acid solution : 0.2 mol/L potassium dihydrogen phosphate solution : acetonitrile : water (0.5:50:400:550)

Gradient: 0 min: 85 %A:

10 min, 85 %A; 40 min, 0 %A;

50 min, 0 %A; 51 min, 85 %A;

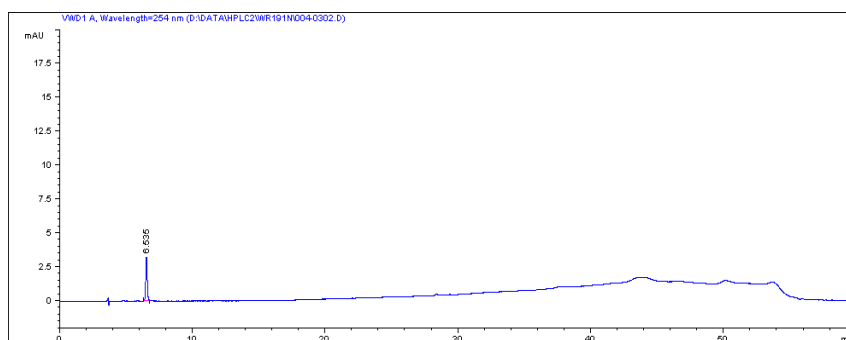
60 min, 85 %A

## Chromatographic conditions

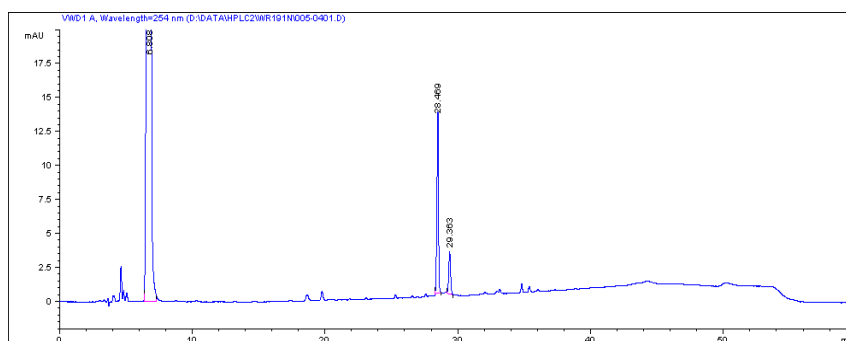
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: see assay
- Flow rate: 1 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR191N004-0302.D



The chromatogram of the test solution--- HPLC2WR191N005-0401.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Ampicillin	6.81	2738.2	4449	/	/
Impurity1	28.47	111.2	268056	68.8	0.88
Impurity2	29.36	30.6	220390	3.8	0.89

# Ampicillin Sodium and Sulbactam Sodium for Injection

Ampicillin (0410-200004), Sulbactam (130430-200305) – Method number WR063

注射用氨苄西林钠舒巴坦钠

## Assay

Test solution: Dissolve an accurately weighed quantity of the well-mixed contents in mobile phase to produce a test solution containing 0.6 mg ampicillin and 0.3 mg sulbactam per mL.

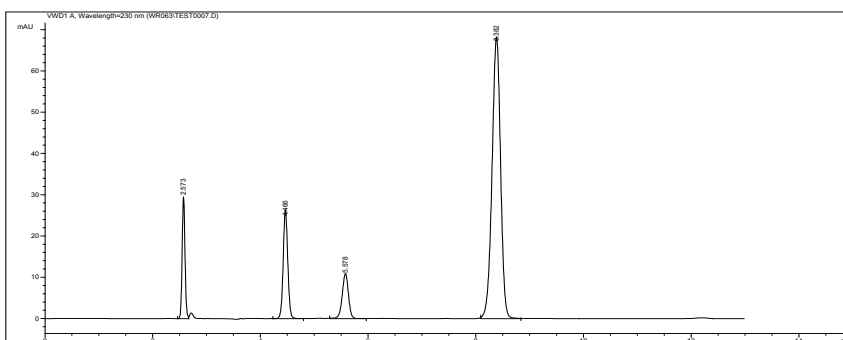
Reference solution: Dissolve an accurately weighed quantity of ampicillin CRS and sulbactam CRS in mobile phase to produce a reference solution of 0.6 mg ampicillin and 0.3 mg sulbactam per mL. Dissolve 6 mg of ampicillin CRS and 3 mg of sulbactam CRS in two separate quantities of 10 mL of 0.01 mol/L sodium hydroxide solution, allow to stand for 30 minutes, adjust to pH 4.0 ± 0.1 with 1 mol/L phosphoric acid. Transfer 5 mL of each solution to a 25 mL volumetric flask, add a quantity of ampicillin CRS and sulbactam CRS (equivalent to 5 mg of ampicillin and 2.5 mg of sulbactam), dilute to volume with mobile phase, mix well and use for the system suitability test.

## Chromatographic conditions

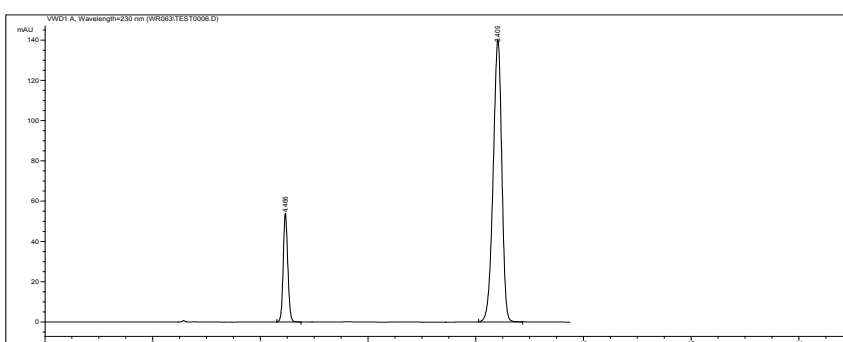
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.02 mol/L sodium dihydrogen phosphate solution (dissolve 2.76 g of sodium dihydrogen phosphate in 950 mL of water, adjust pH to 4.0±0.1 with 1 mol/L phosphoric acid solution, dilute with water to 1000 mL, mix well) : acetonitrile = 92:8
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC2\WR063\TEST007.D



The chromatogram of the test solution --- HPLC2\WR063\TEST006.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Sulbactam-deg	2.57	110.1	11441	/	1.06
Sulbactam	4.47	156.9	13848	15.2	1.04
Ampicillin-deg	5.58	89.0	11404	6.2	0.97
Ampicillin	8.38	754.1	13492	11.3	0.96

# Ampicillin Sodium and Sulbactam Sodium for Injection

Ampicillin (0410-200004), Sulbactam (130430-200305) – Method number WR063

注射用氨苄西林钠舒巴坦钠

## Assay

Test solution: Dissolve an accurately weighed quantity of the substance in mobile phase to produce the test solution containing 3 mg ampicillin and 1.5 mg sultactam per mL.

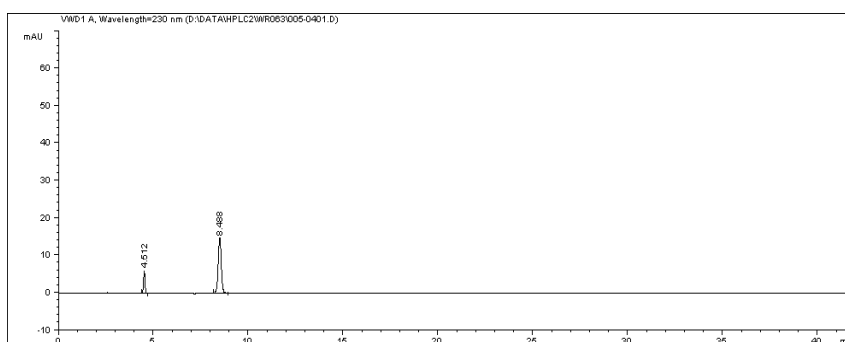
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution containing 30 µg ampicillin and 15 µg sultactam per mL.

## Chromatographic conditions

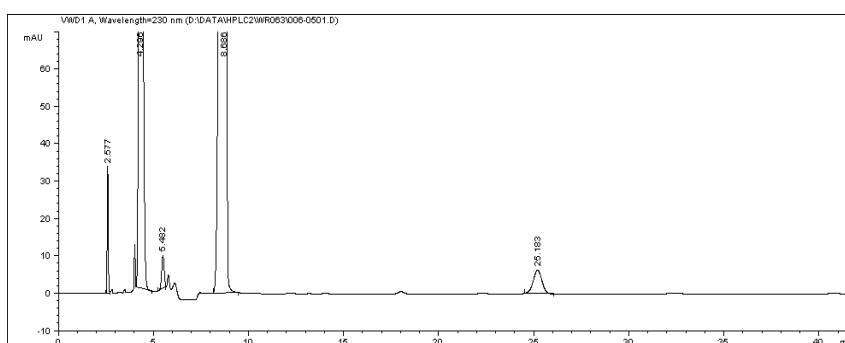
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.02 mol/L sodium dihydrogen phosphate solution (dissolve 2.76 g of sodium dihydrogen phosphate in 950 mL of water, adjust pH to 4.0 ± 0.1 with 1 mol/L phosphoric acid solution, dilute with water to 1000 mL, mix well) : acetonitrile = 92:8
- Flow rate: 1.0 mL/min
- Injection volume: 5 µL
- Column temperature: 30 °C
- Detector wavelength: 230 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability—HPLC2\WR063\005-0401.D



The chromatogram of the test solution--- HPLC2\WR063\006-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Sulbactam-deg	2.58	130.9	11150	/	1.09
Sulbactam	4.30	3079.6	1965	7.1	1.30
Ampicillin-deg	5.48	82.1	8031	3.7	1.08
Ampicillin	8.69	14113.2	5558	9.0	0.75
Impurity	25.18	203.2	14915	25.5	0.96

# Oxacillin Sodium for Injection – 注射用苯唑西林钠

Oxacillin Sodium (0482-9901) – Method number WR166

## Assay

Test solution: Dissolve a quantity of the contents in mobile phase to produce the test solution of 0.1 mg/mL.

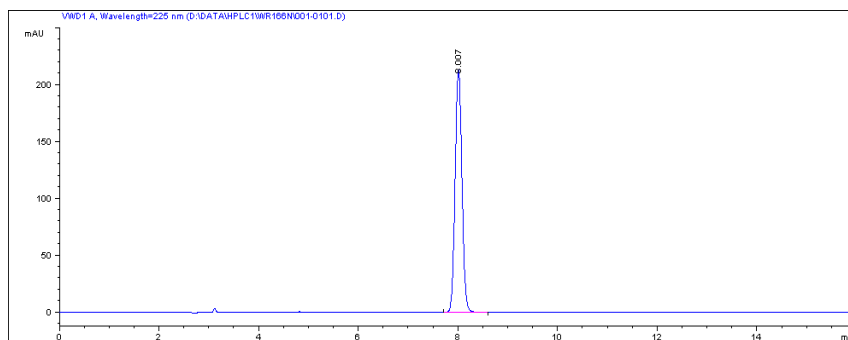
Reference solution: Repeat the procedure using oxacillin sodium CRS to produce the reference solution.

## Chromatographic conditions

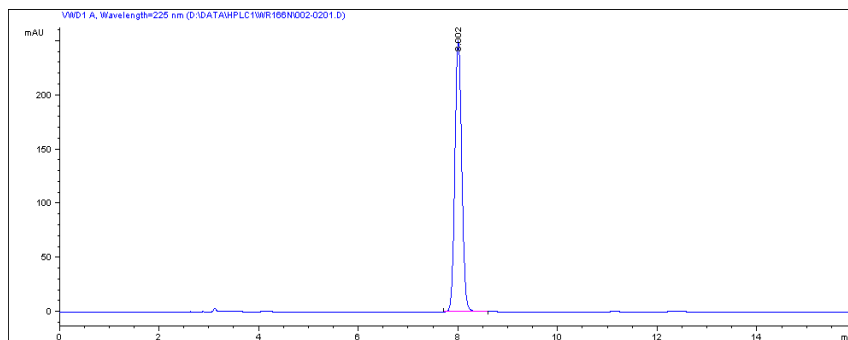
- Column: Agilent ZORBAX SB-Phenyl 4.6X250 mm, 5 µm (880975-912)
- Mobile phase: 0.02 mol/L potassium dihydrogen phosphate solution (adjust pH to 3.6 with phosphoric acid) : acetonitrile : methanol = 60:27.5:12.5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR166N\001-0101



The chromatogram of the test solution --- HPLC1\ WR166N\002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Oxacillin	8.00	2410.0	15671	/	1.05



# Oxacillin Sodium for Injection – 注射用苯唑西林钠

Oxacillin Sodium (0482-9901) – Method number WR166

## Assay

Test solution: Dissolve an accurately weighed quantity of the content in water to produce the test solution of 1 mg/mL.

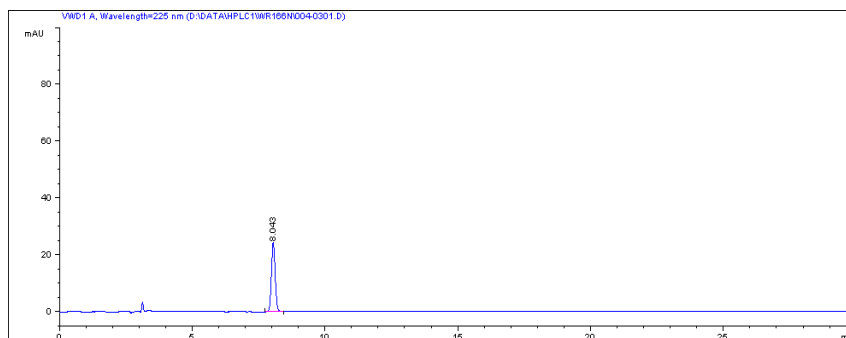
Reference solution: Dilute an accurately measured quantity of the test solution with water to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

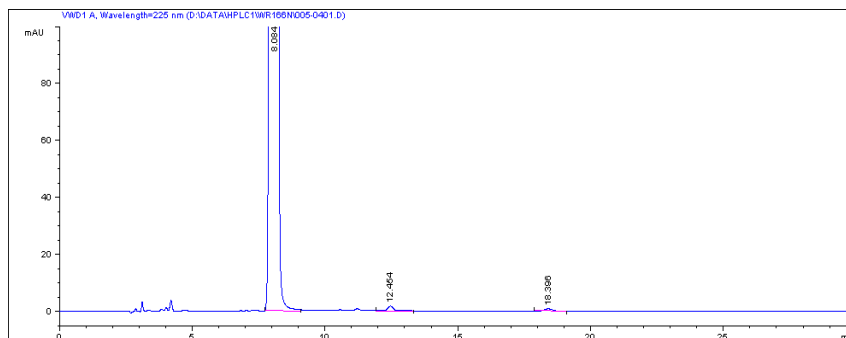
- Column: Agilent ZORBAX SB-Phenyl 4.6x250 mm, 5 µm (880975-912)
- Mobile phase: 0.02 mol/L potassium dihydrogen phosphate solution (adjust pH to 3.6 with phosphoric acid) : acetonitrile : methanol = 60:27.5:12.5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR166N004-0301



The chromatogram of the test solution --- HPLC1\WR166N005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Oxacillin	8.00	2410.0	15671	/	1.05

# Benzathine Benzylpenicillin for Injection – 注射用苄星青霉素

## Benzylpenicillin (0437-9501) – Method number WR058

### Assay

Test solution: Accurately weigh about 53 mg of the mixed contents in a 50 mL volumetric flask, dissolve in 10 mL of acetonitrile and 5 mL of methanol, dilute with 0.05 mol/L phosphate BS to volume, mix well and use as the test solution.

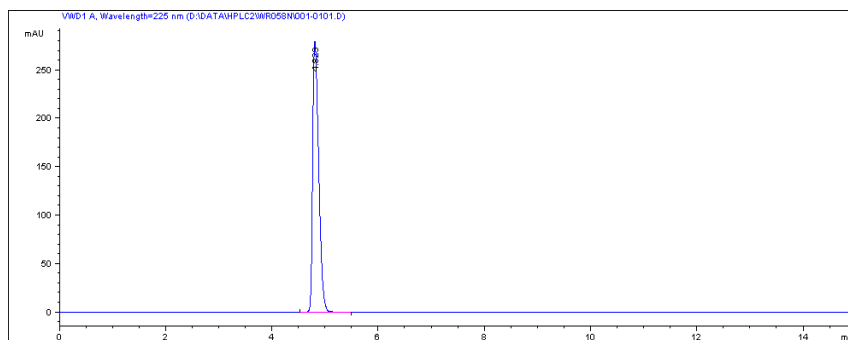
Reference solution: Repeat the procedure using an accurately weighed quantity of about 40 mg of benzylpenicillin CRS to produce the reference solution.

### Chromatographic conditions

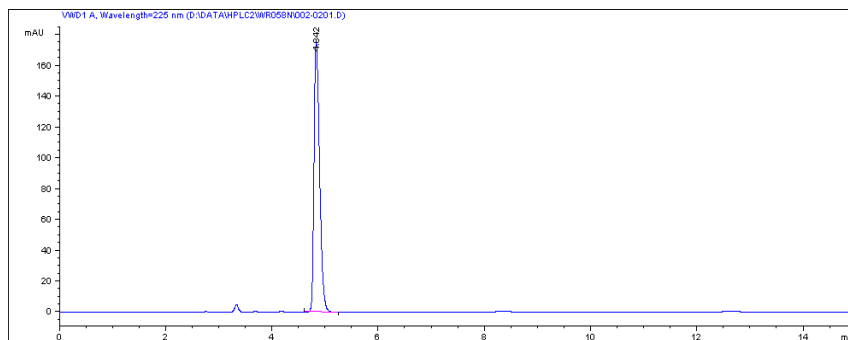
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 μm (990967-902)
- Mobile phase: 0.05 mol/L phosphate BS (dissolve 6.8 g of potassium dihydrogen phosphate in 900 mL of water, adjust pH to 6.0 with 0.1 mol/L sodium hydroxide, dilute with water to 1000 mL) : acetonitrile = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WR058N001-0101



The chromatogram of the test solution--- HPLC2\ WR058N002-0201

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Benzylpenicillin	4.84	1280.4	10202	/	1.24

# Potassium Dehydroandrograpolid Succinate for Injection

Dehydroandrograpolid Succinate (111598-200301) – Method number WA101

## 注射用穿琥宁

### Assay

Test solution: Accurately weigh a quantity of the mixed contents, equivalent to about 10 mg potassium dehydroandrograpolid succinate, in a 100 mL volumetric flask, dissolve and dilute to volume with mobile phase, mix well and use as the test solution.

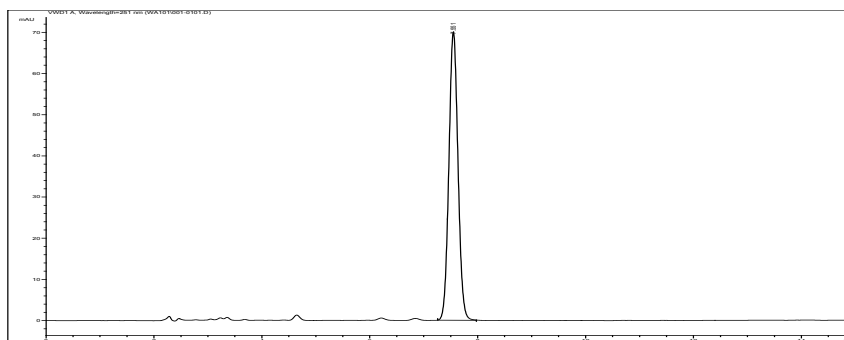
Reference solution: Repeat the procedure using about 10 mg of potassium dehydroandrograpolid succinate CRS dried to constant weight at 60 °C in vacuum to produce reference solution.

### Chromatographic conditions

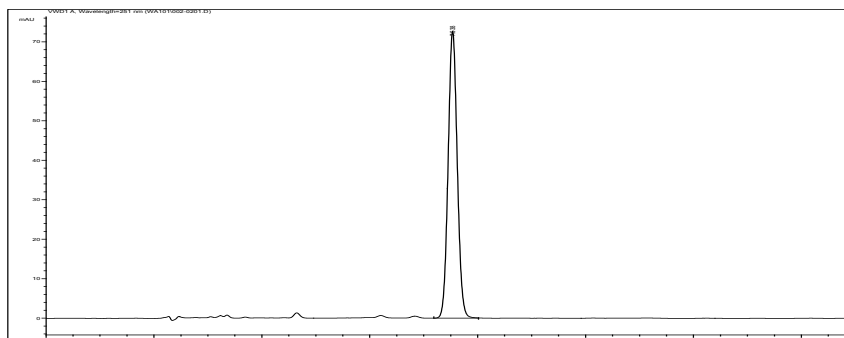
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : 0.05 % potassium dihydrogen phosphate solution (adjust pH to  $2.5 \pm 0.05$  with phosphoric acid) = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 251 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA101\001-0101



The chromatogram of the test solution --- HPLC1\ WA101\002-0201

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dehydroandrograpolid Succinate Sodium	7.54	856.0	9503	/	1.04

# Potassium Dehydroandrograpolide Succinate for Injection

Dehydroandrograpolide succinate (111598-200301) – Method number WA101

注射用穿琥宁

## Assay

Test solution: Dissolve a quantity of the mixed contents in mobile phase to produce the test solution of 0.4 mg of potassium dehydroandrograpolide succinate per mL.

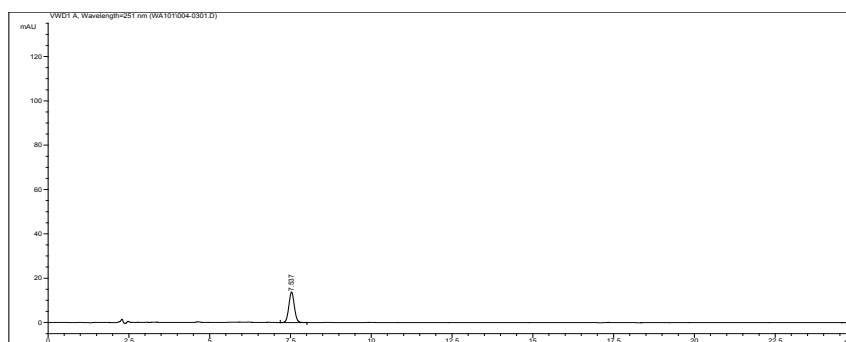
Reference solution: Dilute a quantity of test solution with mobile phase to produce the reference solution of 20 µg/mL.

## Chromatographic conditions

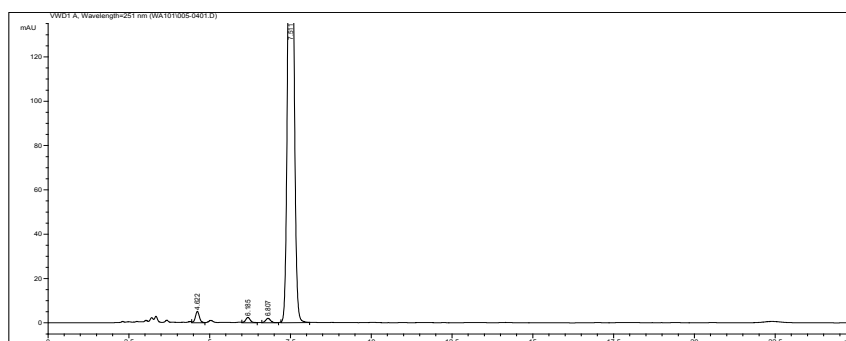
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : 0.05 % potassium dihydrogen phosphate solution (adjust pH to  $2.5 \pm 0.05$  with phosphoric acid) = 65:35
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 251 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA101\004-0301



The chromatogram of the test solution --- HPLC1\ WA101\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Dehydroandrograpolide Succinate Sodium	7.51	3318.5	9436	2.4	1.05
Impurity1	4.62	44.4	7064	/	0.95
Impurity2	6.19	24.1	9778	6.6	1.04
Impurity3	6.81	20.9	10008	2.4	1.03

# Ganciclovir for Injection – 注射用更昔洛韦

Ganciclovir (100380-200301) – Method number WA098

## Assay

Test solution: Dissolve the contents of 5 containers in mobile phase in a 250 mL volumetric flask, dilute to volume and mix well. Dilute an accurately measured quantity with mobile phase to produce the test solution containing 40 µg of ganciclovir per mL.

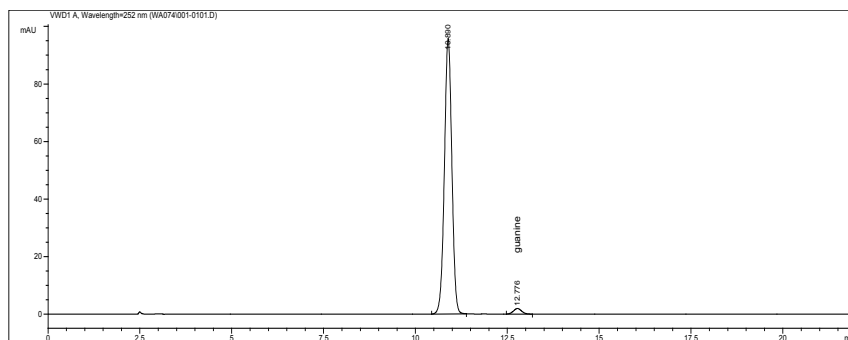
Reference solution: Accurately weigh about 25 mg of ganciclovir CRS dried to constant weight at 105 °C in a 25 mL volumetric flask, add 1 mL of 0.4 % sodium hydroxide solution, dilute with mobile phase to volume, mix well, dilute with mobile phase to produce the reference solution containing 40 µg of ganciclovir CRS per mL.

## Chromatographic conditions

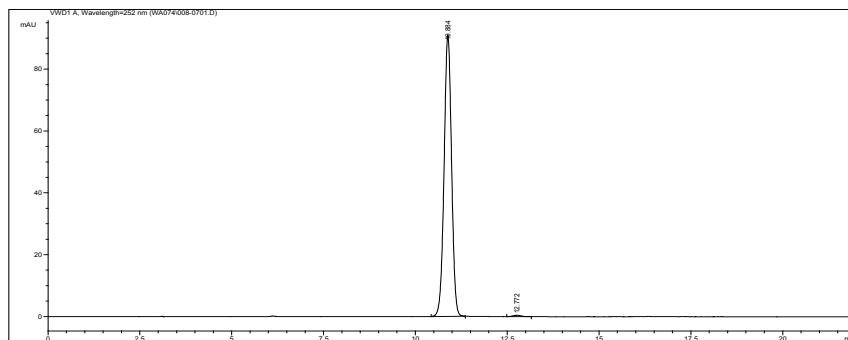
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: water : methanol = 95:5
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 252 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the system suitability ---HPLC1\WA074001-0101



The chromatogram of the test solution--- HPLC1\WA097008-0701

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ganciclovir	10.88	1288.7	14070	/	0.99
guanine	12.77	6.8	1656	4.9	0.97

# Pefloxacin Mesylate for Injection – 注射用甲磺酸培氟沙星

## Pefloxacin (130459-200301) – Method number WA096

### Assay

Test solution: Dissolve an accurately weighed quantity of the mixed contents in water to produce the test solution of 20 µg of pefloxacin per mL.

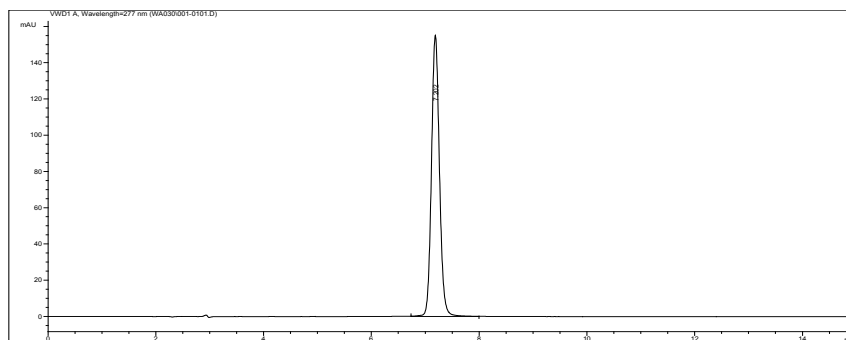
Reference solution: Repeat the procedure using an accurately weighed quantity of pefloxacin CRS to produce the reference solution.

### Chromatographic conditions

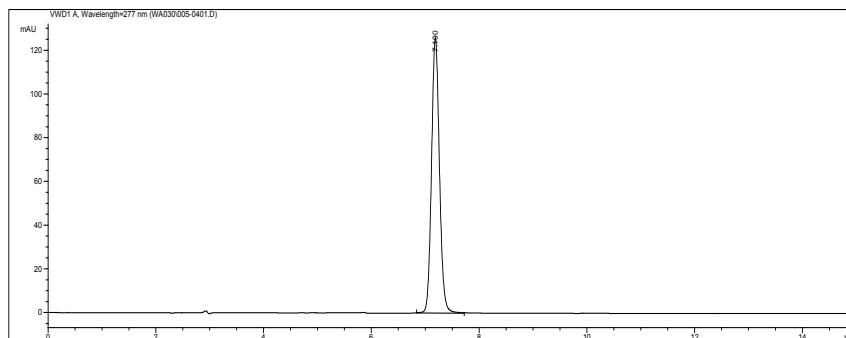
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.04 M potassium dihydrogen phosphate : acetonitrile : 0.05 M tetrabutylammonium bromide (adjust pH to 4.0 with phosphoric acid) = 80:10:10
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 277 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA030\001-0101



The chromatogram of the test solution --- HPLC1\ WA030\005-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Pefloxacin	7.19	1284.2	11634	/	1.07

# Ribavirin for Injection – 注射用利巴韦林

Ribavirin (130459-200301) – Method number WA097

## Assay

Test solution: Accurately weigh a quantity of the mixed contents, dissolve and dilute to produce a solution of 50 µg of ribavirin per mL, mix well and use as the test solution.

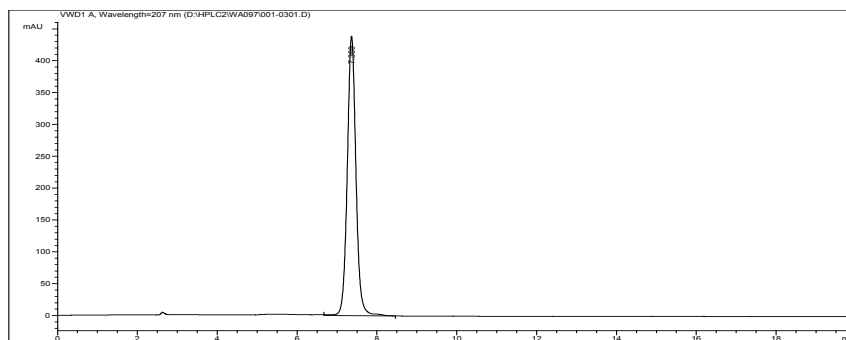
Reference solution: Repeat the procedure using ribavirin CRS dried to constant weight at 105 °C to produce the reference solution.

## Chromatographic conditions

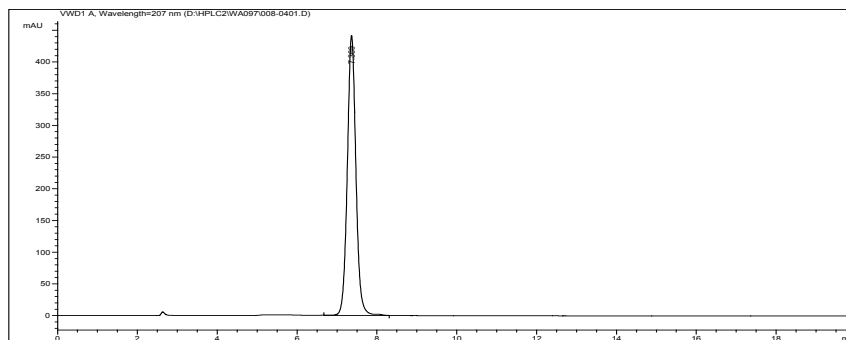
- Column: hydrogen cation-exchange resin HC-75H+
- Mobile phase: water (adjust pH to 2.5±0.1 with dilute sulfate acid)
- Flow rate: 0.4 mL/min
- Injection volume: 20 µL
- Column temperature: 80 °C
- Detector wavelength: 207nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA097\001-0301



The chromatogram of the test solution --- HPLC1\ WA097\008-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Ribavirin	7.37	6629.6	5213	/	1.045

# Vindesine Sulfate for Injection – 注射用硫酸长春地辛

Vindesine sulfate – Method number WA105

## Assay

Test solution: Dissolve and dilute a quantity of the contents with water to produce a solution of 0.1 mg of vindesine sulfate per mL.

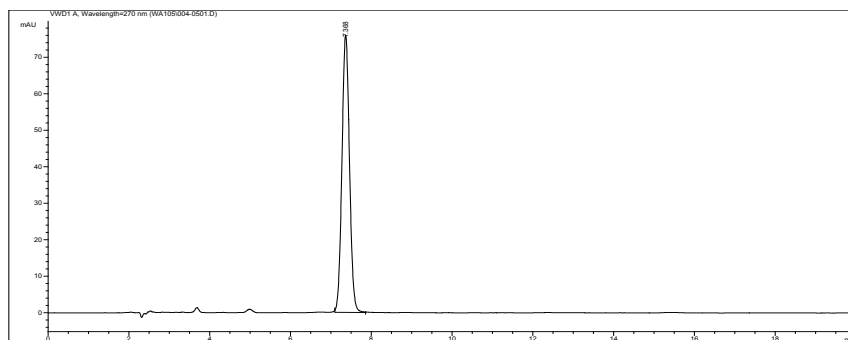
Reference solution: Prepare the reference solution using a quantity of vindesine sulfate CRS, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

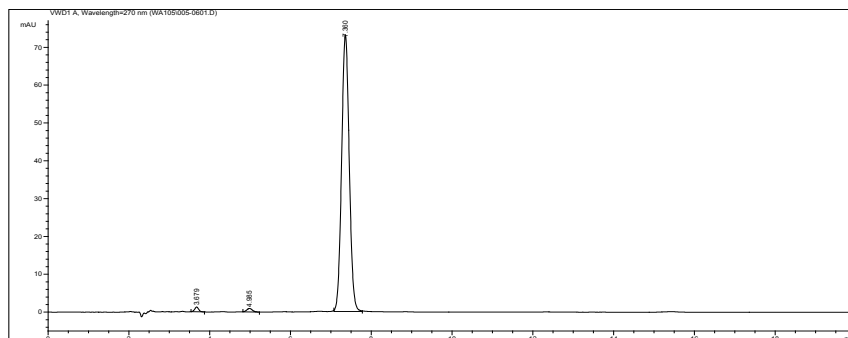
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : 0.05 % dipotassium hydrogen phosphate solution (adjust to pH 6.62 with phosphoric acid) = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 270 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA105\004-0501



The chromatogram of the test solution--- HPLC2\ WA105\005-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vindesine Sulfate	7.36	961.5	7401	/	1.05



# Vindesine Sulfate for Injection – 注射用硫酸长春地辛

Vindesine sulfate – Method number WA105

## Assay

Test solution: Dissolve a quantity of the contents in water to produce the test solution of 1 mg of vindesine sulfate per mL.

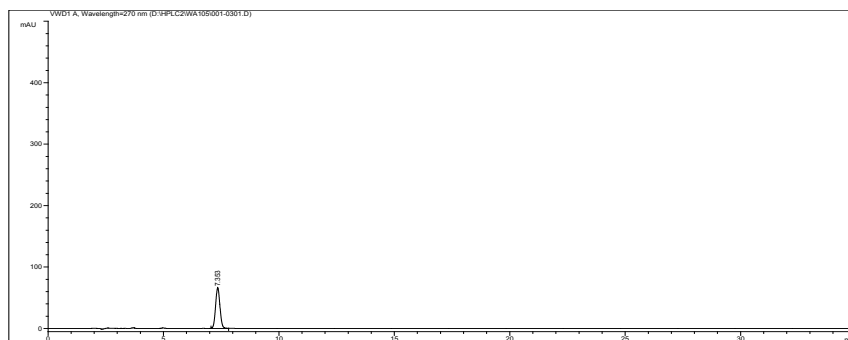
Reference solution: Dissolve a quantity of the contents in water to produce the reference solution of 0.05 mg/mL.

## Chromatographic conditions

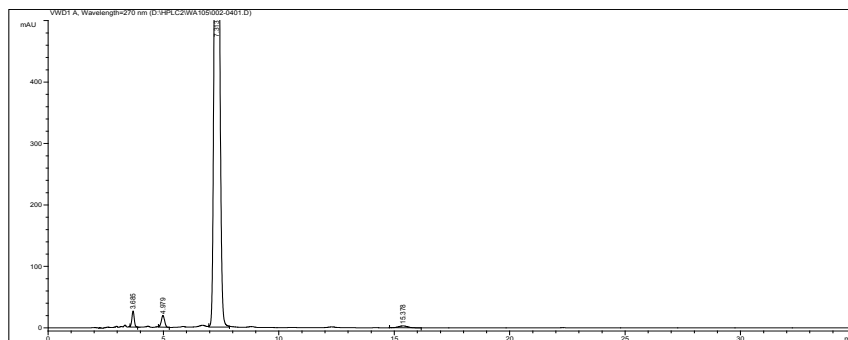
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: methanol : 0.05 % dipotassium hydrogen phosphate solution (adjust to pH 6.62 with phosphoric acid) = 75:25
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 270 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA105\001-0301



The chromatogram of the test solution--- HPLC2\ WA105\002-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Vindesine Sulfate	7.31	19844.9	7304	7.8	1.08
Impurity1	3.69	184.1	6598	/	0.96
Impurity2	4.98	189.9	5939	5.9	0.94
Impurity3	15.38	81.3	7883	15.6	0.98

# Etimicin Sulfate for Injection – 注射用硫酸依替米星

Etimicin, Netilmicin – Method number WA324

## Assay

Test solution: Dissolve an accurately weighed quantity of the contents in water to produce the test solution of 0.5 mg of etimicin per mL.

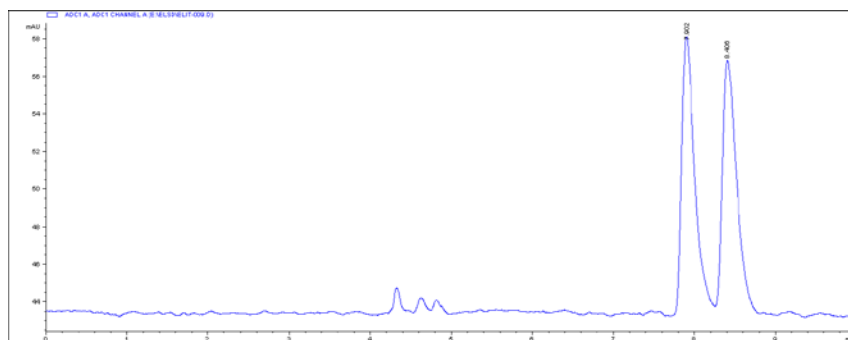
Reference solution: Repeat the procedure to produce the reference solution.

## Chromatographic conditions

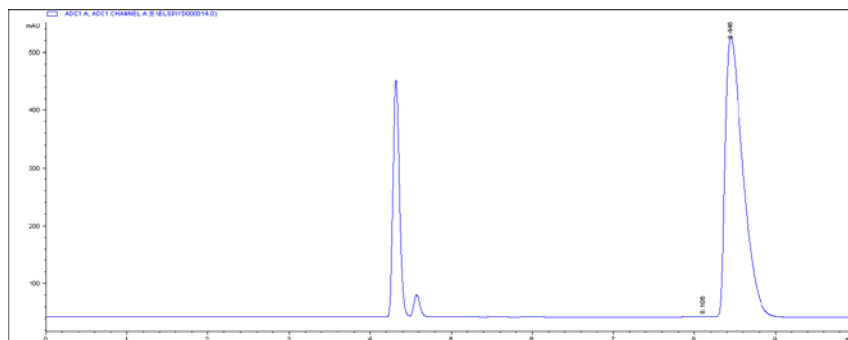
- Column: ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 1 % trifluoroacetate solution
- Flow rate: 0.6 mL/min
- Injection volume: 20 µL
- Column temperature: 20 °C
- Evaporator tube temperature: 115 °C
- Air flow rate: 3.5 mL/min

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 35900E A/D converter
- ELSD Alltech 2000
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability



The chromatogram of the test solution

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Netilmicin	8.102	926.4	14818		1.2
Etimicin	8.642	2096.6	11874	1.85	1.3

# Cloxacillin Sodium for Injection – 注射用氯唑西林钠

Cloxacillin Sodium (0423-9902) – Method number WR197

## Assay

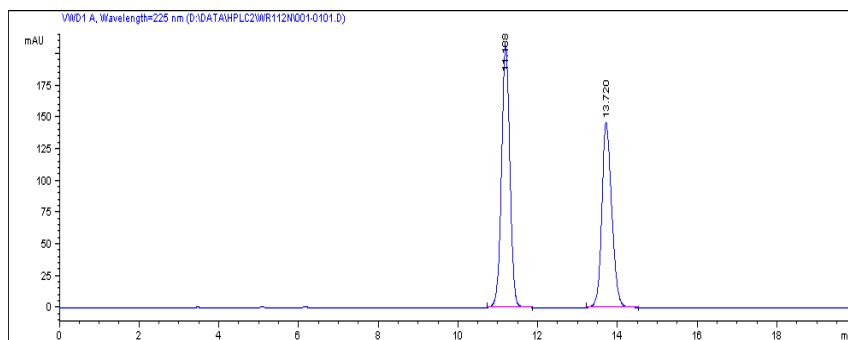
Test solution: Dissolve an accurately weighed quantity of the contents in mobile phase to produce a test solution of 0.1 mg/mL. Dissolve a quantity of cloxacillin CRS and flucloxacillin CRS in mobile phase to produce a solution of 0.1 mg/mL and use for the system suitability test.

## Chromatographic conditions

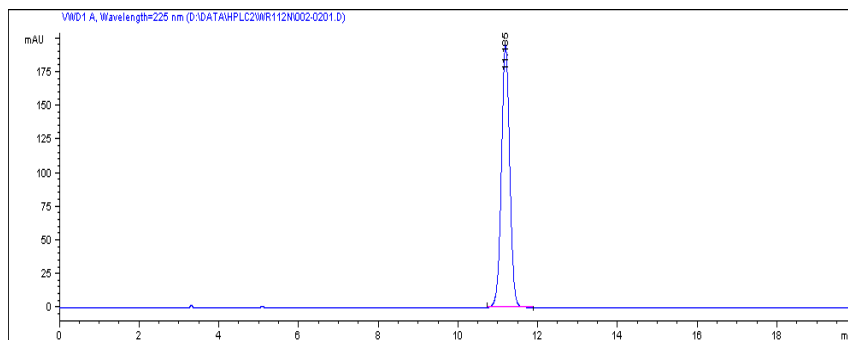
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.02 mol/L potassium dihydrogen phosphate solution (pH 5.0): acetonitrile = 75:25
- Flow rate: 1 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability --- HPLC2WR112N001-0101.D



The chromatogram of the test solution --- HPLC2WR112N002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cloxacillin Sodium	11.19	3012.4	13917	/	0.99
Flucloxacillin Sodium	13.72	2524.2	15182	6.12	1.12

# Cloxacillin Sodium for Injection – 注射用氯唑西林钠

Cloxacillin Sodium (0423-9902) – Method number WR197

## Assay

Test solution: Dissolve a quantity in mobile phase to produce the test solution of 1 mg/mL.

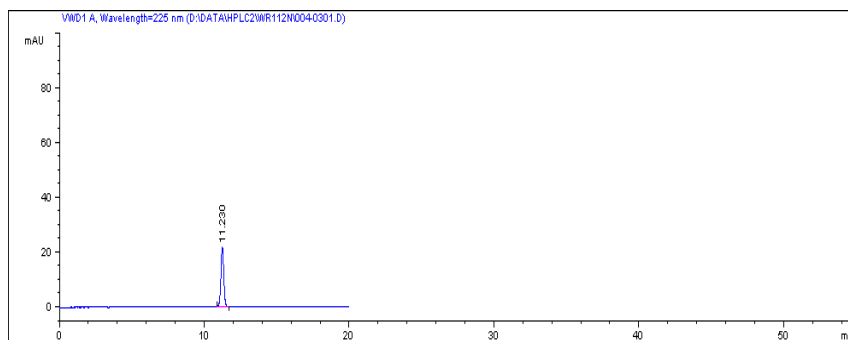
Reference solution: Dissolve a quantity in mobile phase to produce the reference solution of 10 µg/mL.

## Chromatographic conditions

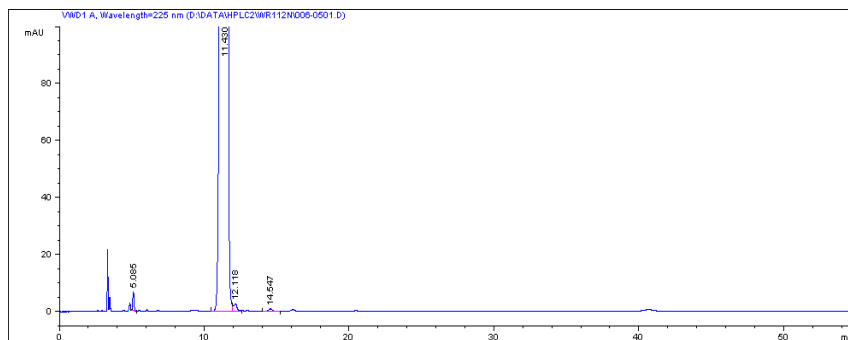
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.02 mol/L potassium dihydrogen phosphate solution (pH 5.0): acetonitrile = 75:25
- Flow rate: 1 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR112N004-0301.D



The chromatogram of the test solution--- HPLC2WR112N006-0501.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cloxacillin Sodium	11.43	27017.3	3752	13.8	0.76
Impurity1	5.09	46.4	13791	/	0.98
Impurity2	12.12	46.0	11557	/	/
Impurity3	14.55	16.9	16158	5.3	0.89

# Meropenem for Injection – 注射用美罗培南

Meropenem (130506-200401) – Method number WA289

## Assay

Test solution: Dissolve a quantity of the mixed contents in mobile phase to produce the test solution of 0.5 mg/mL.

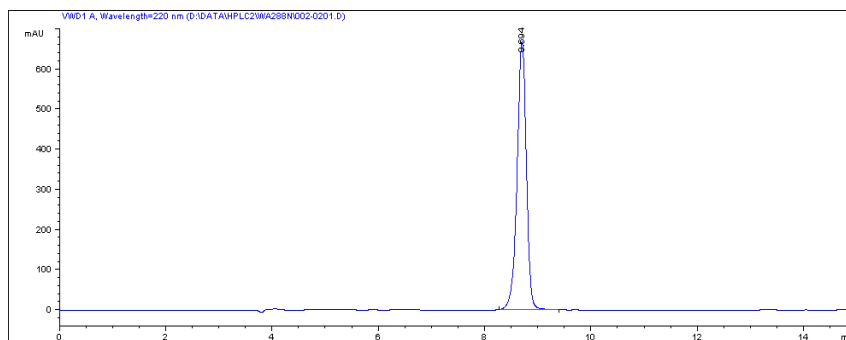
Reference solution: Repeat the procedure using meropenem CRS to produce the reference solution.

## Chromatographic conditions

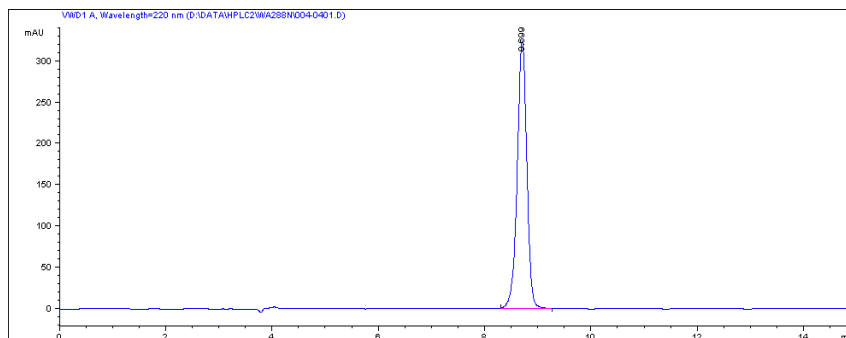
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.3 % triethylamine solution (measure 3.0 mL of triethylamine in 900 mL water, adjust pH to 5.0 with phosphoric acid, dilute with water to 1000 mL) : acetonitrile = 93:7
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA288N002-0201



The chromatogram of the test solution--- HPLC2\ WA288N004-0401

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Meropenem	8.70	4092.9	12006	/	0.95

# Meropenem for Injection – 注射用美罗培南

Meropenem (130506-200401) – Method number WA289

## Assay

Test solution: Dissolve a quantity in mobile phase to produce the test solution of 5 mg/mL.

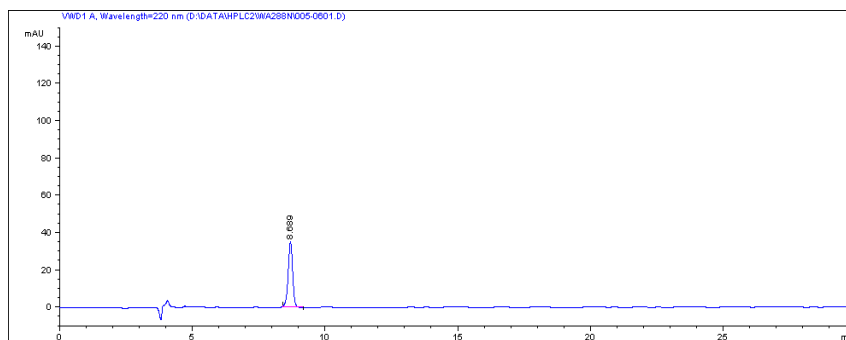
Reference solution: Dilute an accurately measured quantity of the test solution with mobile phase to produce the reference solution of 25 µg/mL.

## Chromatographic conditions

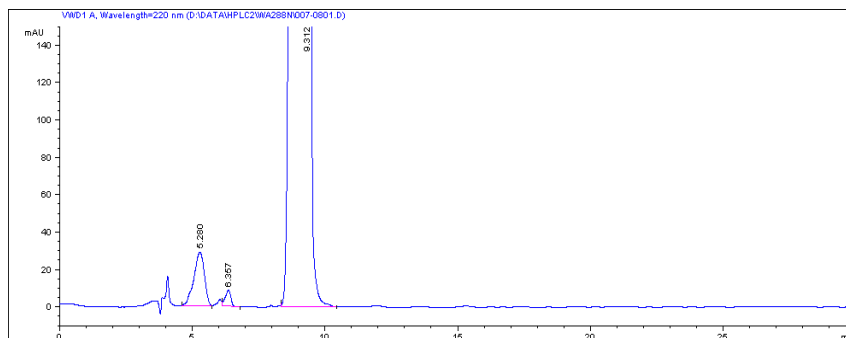
- Column: Agilent ZORBAX Eclipse XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: 0.3 % triethylamine solution (measure 3.0 mL of triethylamine in 900 mL water, adjust pH to 5.0 with phosphoric acid, dilute with water to 1000 mL) : acetonitrile = 93:7
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WA288N005-0601



The chromatogram of the test solution--- HPLC2\WA288N007-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	(N)	(Rs)	(USP Tf)
Meropenem	9.31	77172.9	/	3.6	/
Degradation Product	5.28	804.1	866	/	0.84
Impurity	6.36	130.6	3801	1.9	0.91

# Alprostadil for Injection – 注射用前列地尔

## Alprostadil (ARCOS) – Method number WA100

### Assay

Test solution: Add an accurately measured quantity of 25 % ethanol solution to 3 injections to produce the test solution of 0.1 mg of alprostadil per mL.

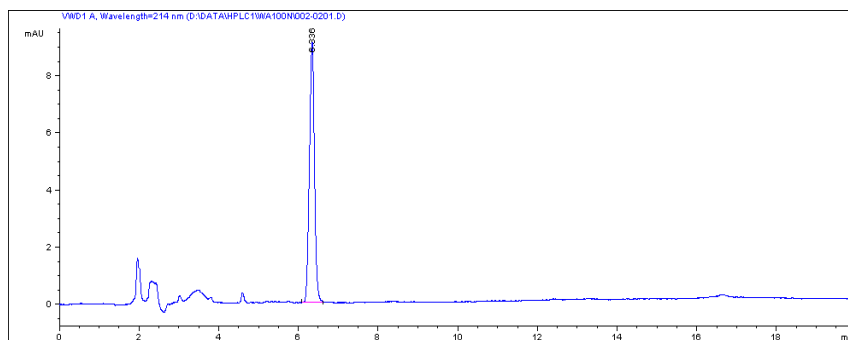
Reference solution: Dissolve a quantity of alprostadil CRS dried to constant weight in vacuum with P<sub>2</sub>O<sub>5</sub> in 25 % ethanol to produce the reference solution of 0.1 mg/mL.

### Chromatographic conditions

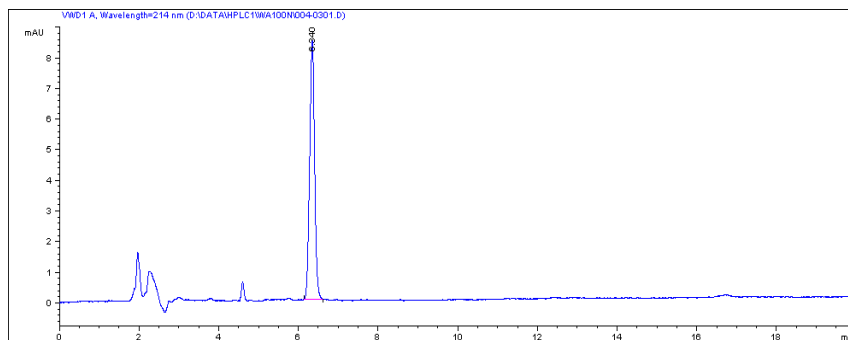
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: acetonitrile : 0.02 mol/L potassium dihydrogen phosphate (pH 4.9) = 40:60
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL
- Column temperature: 30 °C
- Detector wavelength: 214 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA100N002-0201



The chromatogram of the test solution --- HPLC1\ WA100N004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Alprostadil Sodium	6.34	73.6	12968	/	1.00

# Benzylpenicillin Potassium for Injection – 注射用青霉素钾

## Benzylpenicillin Potassium (0437-9501) – Method number WR062

### Assay

Test solution: Dissolve an accurately weighed quantity of contents and mix well to produce the test solution of about 0.5 mg/mL.

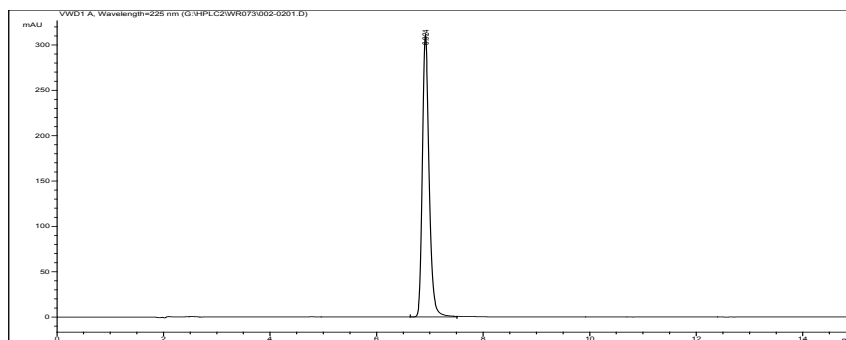
Reference solution: Dissolve a quantity of benzylpenicillin potassium CRS in water to produce the reference solution of 0.2 mg/mL.

### Chromatographic conditions

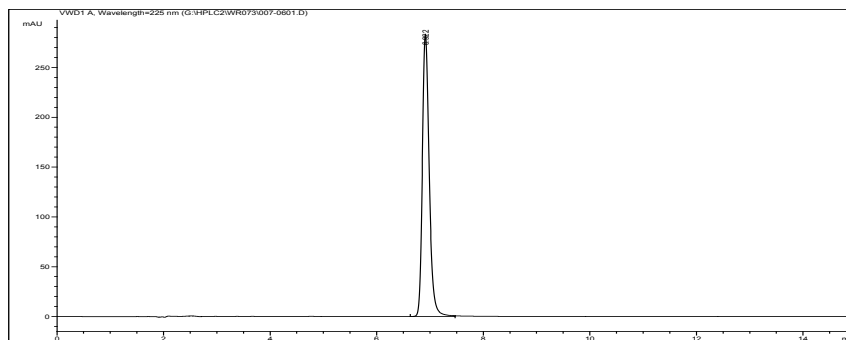
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 μm (880975-902)
- Mobile phase: 0.1 mol/L phosphate BS (pH 2.50) : acetonitrile = 35:65
- Flow rate: 1.0 mL/min Injection volume: 10 μL
- Column temperature: 25 °C
- Detector wavelength: 225 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR073002-0201.D



The chromatogram of the test solution --- HPLC2WA073007-0601.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Benzylpenicillin Potassium	6.92	2533.0	14038	/	1.25



# Benzylpenicillin Sodium for Injection – 注射用青霉素钠

Benzylpenicillin Sodium (0437-9501) – Method number WR061

## Assay

Test solution: Dissolve an accurately weighed quantity of contents and mix well to produce the test solution of about 0.5 mg/mL.

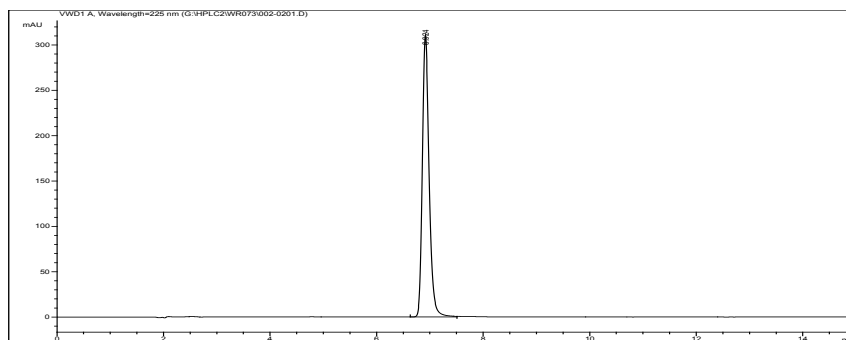
Reference solution: Dissolve a quantity of benzylpenicillin potassium CRS in water to produce the reference solution of 0.2 mg/mL.

## Chromatographic conditions

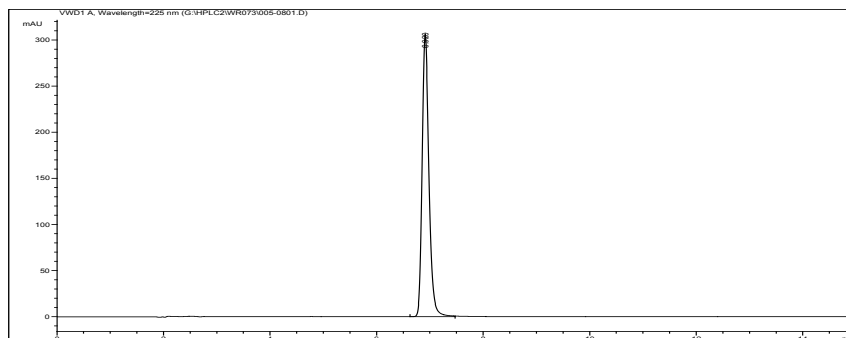
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: 0.1 mol/L phosphate BS (pH 2.50) : acetonitrile = 35:65
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 25 °C
- Detector wavelength: 225 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR073002-0201.D



The chromatogram of the test solution --- HPLC2WR073005-0801.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Benzylpenicillin Sodium	6.92	2719.8	14365	/	1.25

# Adenosine Disodium Triphosphate for Injection

Adenosine disodium triphosphate – Method number WA233

注射用三磷酸腺苷二钠

## Assay

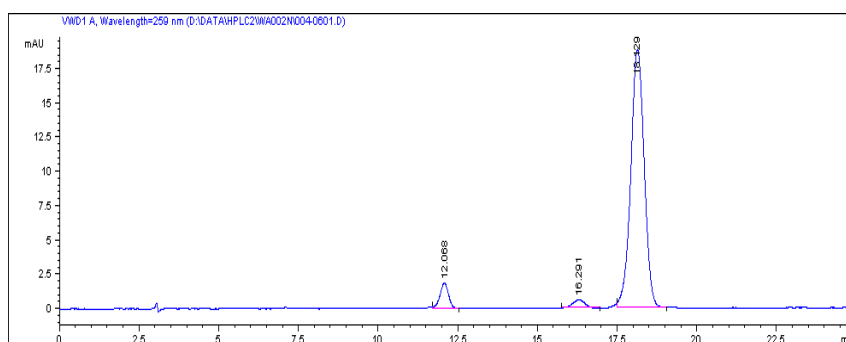
Test solution: Dissolve an accurately measured quantity of injection fluid in mobile phase to produce the test solution of 40 µg/mL.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: methanol : 0.2 mol/L phosphate BS (dissolve 35.8 g of disodium hydrogen phosphate and 13.6 g of potassium dihydrogen phosphate in 900 mL of water, adjust pH to 7.0 with 1 mol/L sodium hydroxide solution, add 1.61 g of tetrabutylammonium bromide, add water to 1000 mL) = 8:92 Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 35 °C
- Detector wavelength: 259 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the test solution---HPLC2WA002N004-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Adenosine Disodium monophosphate	12.07	34.0	10009	/	0.91
Adenosine Disodium diphosphate	16.29	16.3	8059	7.0	0.92
Adenosine Disodium triphosphate	18.13	556.5	9133	2.5	0.97

# Cefradine for Injection – 注射用头孢拉定

Cefradine (130427-200306) – Method number WR143

## Assay

Test solution: Dissolve a quantity of the contents in mobile phase to produce the test solution of 1 mg/mL.

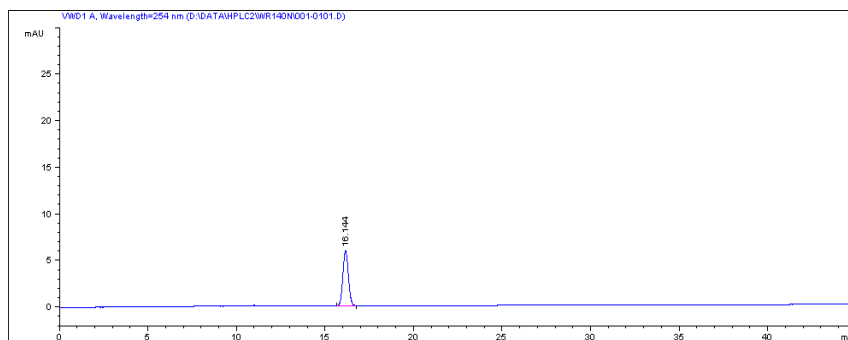
Reference solution: Dissolve a quantity of the contents in mobile phase to produce the reference solution of 5 µg/mL.

## Chromatographic conditions

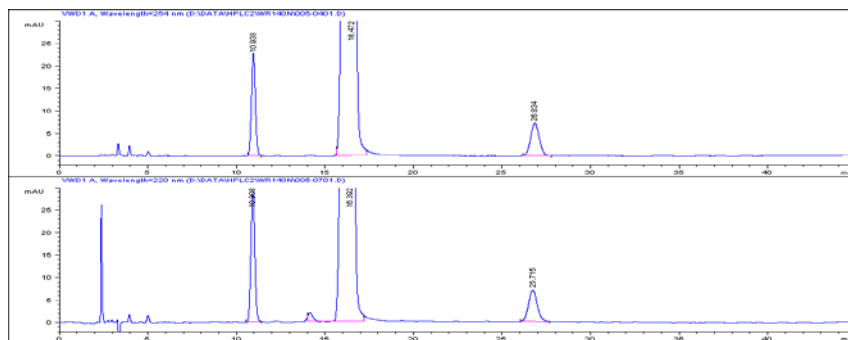
- Column: Agilent ZORBAX SB-C18 4.6×250 mm, 5 µm (880975-902)
- Mobile phase: water : methanol : 3.86 % sodium acetate solution : 4 % solution of acetic acid = 1564:400:30:6
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 254/220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2WR140N001-0101



The chromatogram of the test solution--- HPLC2WR140N 005-0401

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity1	10.94	353.6	11720	/	1.06
Cefradine	16.47	20323.6	9044	10.0	0.75
Impurity2	26.83	248.2	14520	13.1	1.06

# Cefathiamidine for Injection – 注射用头孢硫脒

Cefathiamidine (130523-200201) – Method number WA095

## Assay

Test solution: Dissolve a quantity of the well-mixed contents in mobile phase to produce the test solution of 0.5 mg/mL.

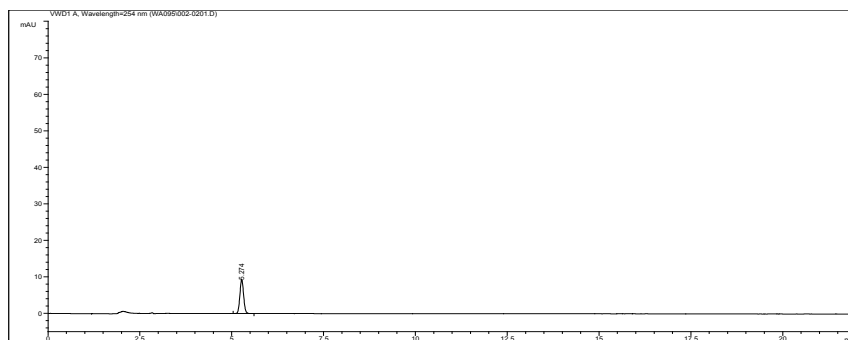
Reference solution: Dilute an accurately measured quantity of test solution with mobile phase to produce the reference solution of 5 µg/mL.

## Chromatographic conditions

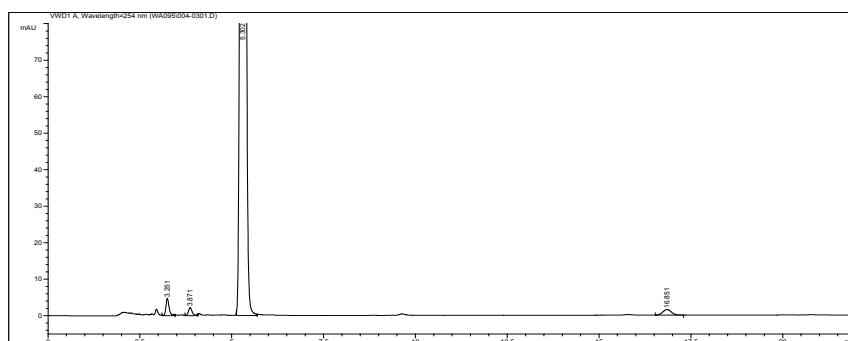
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: phosphate BS (dissolve 2.76 g of anhydrous disodium hydrogen phosphate and 1.29 g of citric acid in 1000 mL of water) : acetonitrile = 80:20
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WA095\002-0201



The chromatogram of the test solution --- HPLC1\WA095\004-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefathiamidine	5.30	5796.8	12503	8.0	1.07
Impurity1	3.25	24.6	8384	/	1.25
Impurity2	3.87	13.3	8377	4.0	/
Impurity3	16.85	24.8	24232	37.0	1.03

# Cefoperazone Sodium for Injection – 注射用头孢哌酮钠

Cefoperazone (130420-200304) – Method number WR145

## Assay

Test solution: Dissolve an accurately weighed quantity of the contents in mobile phase and dilute to produce the test solution containing 0.5 mg/mL.

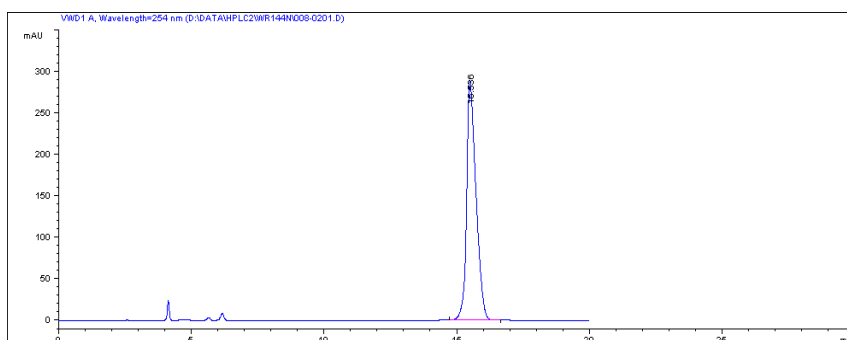
Reference solution: Dissolve a quantity of cefoperazone CRS in mobile phase to produce the reference solution, in which the concentration is equivalent to the test solution.

## Chromatographic conditions

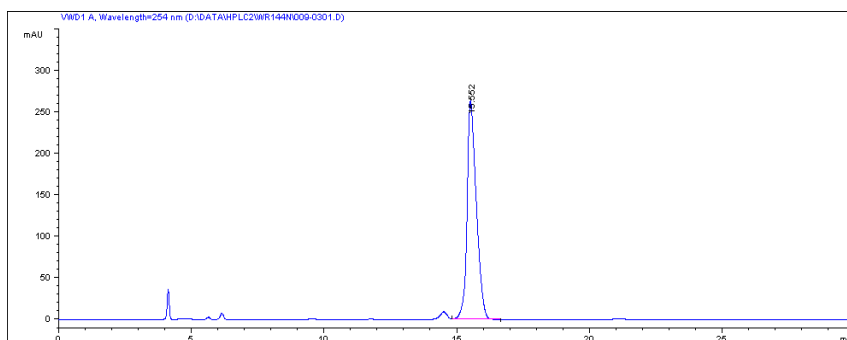
- Column: Agilent ZORBAX SB-Aq 4.6x250 mm, 5  $\mu$ m (880975-914)
- Mobile phase: triethylamine acetic acid solution (dissolve 1.4 mL of triethylamine and 0.57 mg of glacial acetic acid in 8 mL of water, mix well, dilute 6  $\mu$ L with water to 410 mL, adjust pH to 3.0 $\pm$ 0.2 with glacial acetic acid) : acetonitrile = 82:18
- Flow rate: 1.0 mL/min
- Injection volume: 10  $\mu$ L
- Column temperature: 30  $^{\circ}$ C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC2WR144N008-0201



The chromatogram of the test solution ---HPLC2WR144N009-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Cefoperazone	15.55	6402.5	9351	1.9	1.12

# Cefoperazone Sodium for Injection – 注射用头孢哌酮钠

Cefoperazone (130420-200304) – Method number WR145

## Assay

Test solution: Dissolve a quantity of the well-mixed contents in mobile phase to produce the test solution of 0.5 mg/mL.

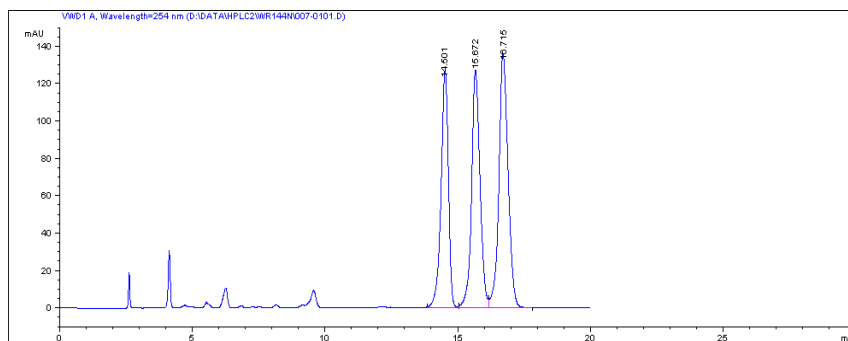
Reference solution: Dilute an accurately measured quantity of test solution with mobile phase to produce the reference solution of 5 µg/mL.

## Chromatographic conditions

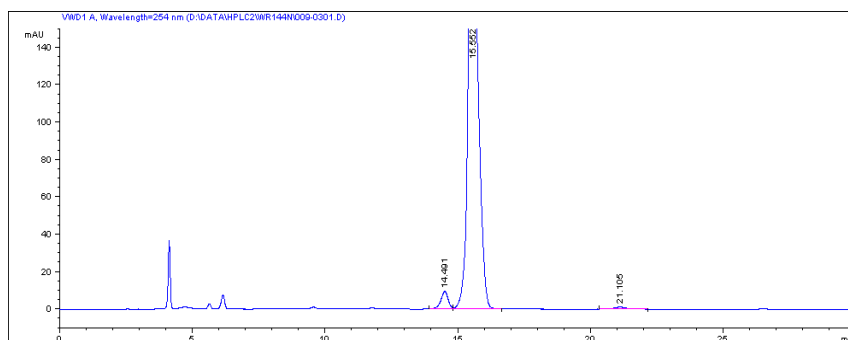
- Column: Agilent ZORBAX SB-Aq 4.6x250 mm, 5 µm (880975-914)
- Mobile phase: triethylamine acetic acid solution (dissolve 1.4 mL of triethylamine and 0.57 mg of glacial acetic acid in 8 mL of water, mix well, dilute 6µL with water to 410 mL, mix well, adjust pH to 3.0±0.2 with glacial acetic acid) : acetonitrile = 82:18
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of system suitability---HPLC2\WR144N007-0101



The chromatogram of the test solution---HPLC2\WR144N009-0301

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefoperazone	15.55	6402.5	9351	1.9	1.12
Cefoperazone degraded product B	14.49	181.4	13720	/	0.95

# Cefoperazone Sodium and Sulbactam Sodium for Injection

Cefoperazone (130420-200304); Sulbactam (130430-200305) – Method number WR057

注射用头孢哌酮钠舒巴坦钠

## Assay

Dissolve a quantity of cefoperazone CRS and sulbactam CRS in a small amount of phosphate BS (mix 39.0 mL of 0.2 mol/L sodium dihydrogen phosphate solution with 61.0 mL of disodium hydrogen phosphate solution, adjust pH to 7.0 with phosphoric acid) and dilute with mobile phase to produce a solution containing 1 mg each of the two substances per mL. Heat for 30 minutes at 60 °C on a water bath and use for the system suitability test. Test solution: Accurately weigh a quantity of the well-mixed contents, equivalent to about 100 mg of cefoperazone, in a 200 mL volumetric flask, dissolve and dilute with mobile phase to volume, mix well and use as the test solution.

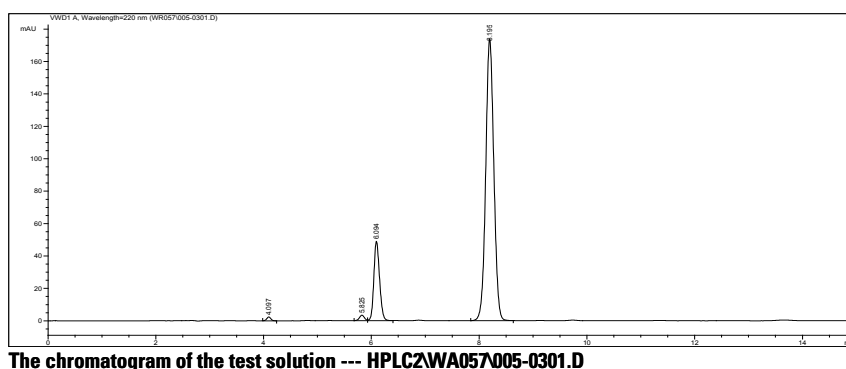
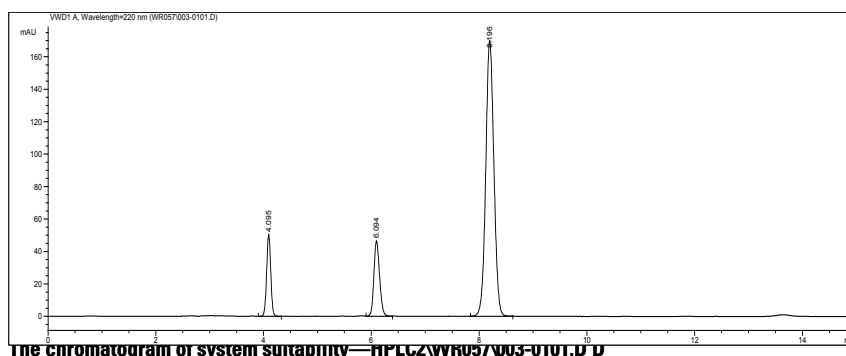
Reference solution: Dissolve about 25 mg each of cefoperazone CRS and sulbactam CRS in 2 mL of phosphate BS (prepared as described above) in a 50 mL volumetric flask, dilute to volume with mobile phase, mix well and use as the reference solution.

## Chromatographic conditions

- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.005 M tetrabutylammonium hydroxide solution (to 26.4 mL of 10 % tetrabutylammonium hydroxide solution or 6.6 mL of 40 % tetrabutylammonium hydroxide solution add 800 mL of water, adjust pH to 4.0 with 1 M phosphoric acid solution, dilute with water to 2000 mL) : acetonitrile (65:35)
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefoperazone	8.20	1818.5	12912	8.60	1.009
Sulbactam	6.09	360.3	16510	11.64	1.073
Cefoperazone degradation	4.10	12.5	14323	/	1.02

# Cefoperazone Sodium and Sulbactam Sodium for Injection

Cefoperazone (130420-200304); Sulbactam (130430-200305) – Method number WR057

注射用头孢哌酮钠舒巴坦钠

## Assay

Test solution: Dissolve a quantity of the substance in the mobile phase to produce the test solution of 4 mg/mL.

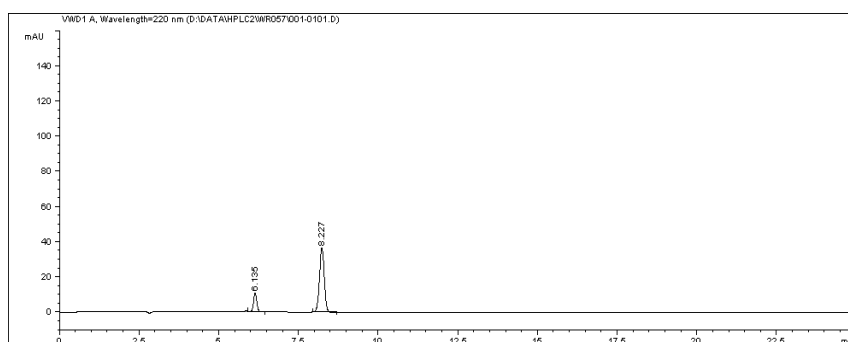
Reference solution: Dissolve a quantity of the substance in the mobile phase to produce the reference solution of 0.04 mg/mL.

## Chromatographic conditions

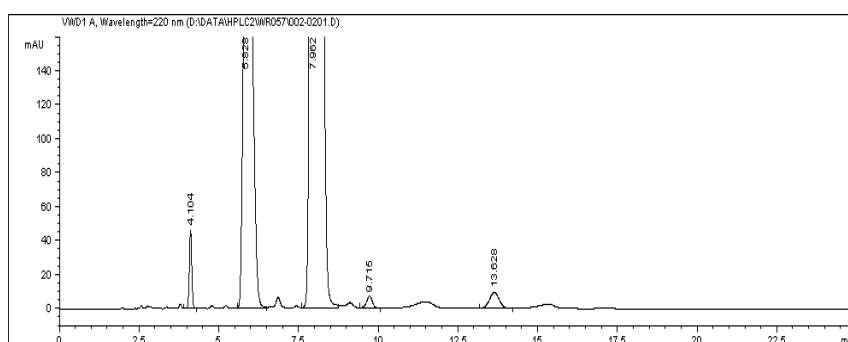
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: 0.005 M tetrabutylammonium hydroxide solution (to 26.4 mL of 10 % tetrabutylammonium hydroxide solution or 6.6 mL of 40 % tetrabutylammonium hydroxide solution add 800 mL of water, adjust pH to 4.0 with 1 M phosphoric acid solution, dilute with water to 2000 mL) : acetonitrile (65:35)  
Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 220 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution—HPLC2WR057001-0101.D



The chromatogram of the test solution --- HPLC2WA057002-0201.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefoperazone	7.96	36021.8	4928	5.3	1.62
Sulbactam	5.83	7564.8	4423	7.0	1.71
Cefoperazone degradation	4.10	249.7	14034	/	1.01
Impurity2	9.72	90.7	14228	4.5	0.90
Impurity3	13.63	191.4	10028	9.0	1.02



# Cefazolin Sodium for Injection – 注射用头孢唑林钠

Cefazolin Sodium (0421-9603) – Method number WR146

## Assay

Test solution: Accurately weigh about 50 mg of the substance in a 20 mL volumetric flask, dissolve and dilute to volume with mobile phase, mix well and use as the test solution.

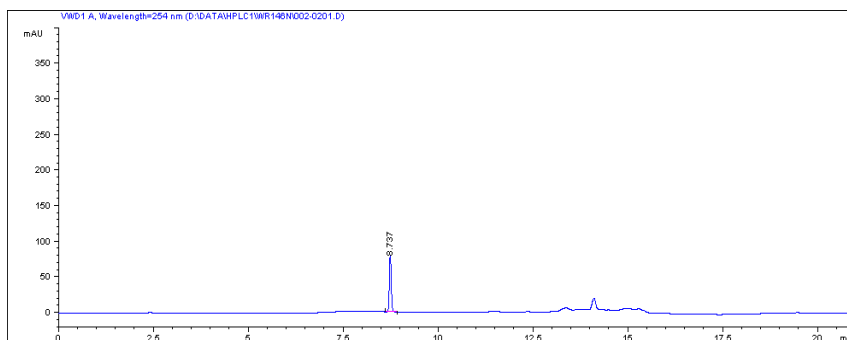
Reference solution: Accurately measure 1 mL of the test solution in a 100 mL volumetric flask, dilute with mobile phase, mix well and use as the reference solution. Dissolve about 10 mg of the contents in 10 ml of 0.2 % sodium hydroxide solution. Allow to stand for 15-30 minutes. Accurately measure 1 mL of the solution and dilute to 20 mL with mobile phase. Mix well and use for the system suitability test.

## Chromatographic conditions

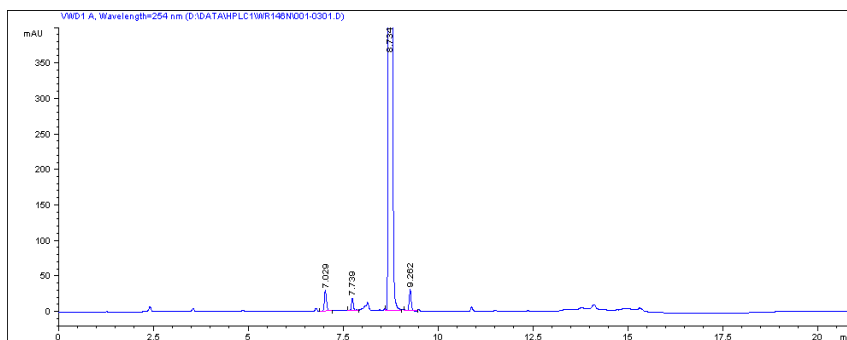
- Column: Agilent ZORBAX SB-Aq 4.6×50mm, 5 µm (880975-902)
- Mobile phase: A: 1.454 % disodium hydrogen phosphate and 0.353 % potassium dihydrogen phosphate B: acetonitrile Gradient: 0 min, 98 %A; 2 min, 98 %A; 4 min, 90 %A; 10 min, 70 %A; 11.5 min, 50 %A; 12 min, 50 %A; 15 min, 98 %A; 21 min, 98 A%
- Flow rate: 1.2 mL/min
- Injection volume: 10 µL
- Column temperature: 45 °C
- Detector wavelength: 254 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR146N002-0201.D



The chromatogram of the test solution --- HPLC1\WR146N001-0301.D

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Cefazolin Sodium	8.73	18302.7	75630	9.4	1.12
Impurity1	7.03	118.1	74341	/	1.12
Impurity2	7.74	53.0	133118	7.5	1.07
Impurity3	9.26	110.4	152528	4.8	1.09

# Calcium Folate for Injection – 注射用亚叶酸钙

## Calcium Folate – Method number WR155

### Assay

Test solution: Dissolve the contents of 5 containers in water to dissolve the calcium folinate, transfer and dilute to produce a solution of 0.1 mg/mL, filter and use the filtrate as the test solution.

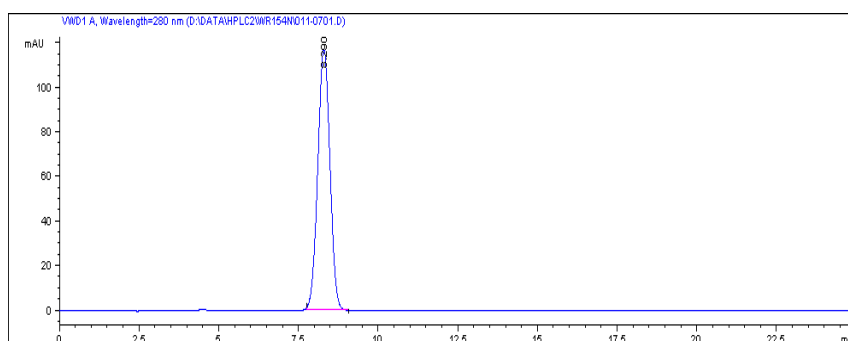
Reference solution: Repeat the procedure using calcium folinate CRS to produce the reference solution.

### Chromatographic conditions

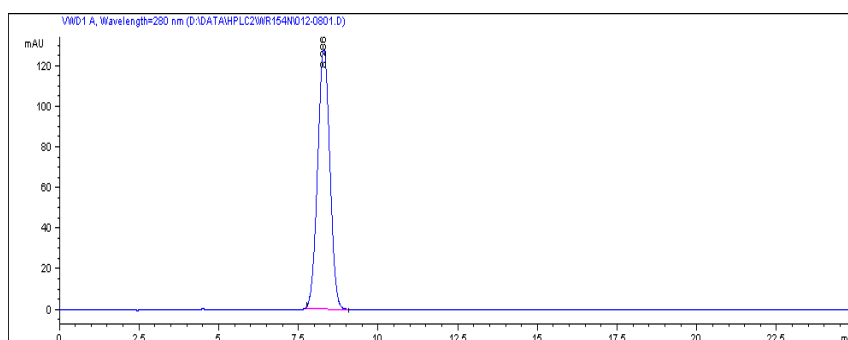
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : sodium dihydrogen phosphate BS containing 0.1 % tetrabutylammonium hydroxide solution (dissolve 2.0 mL of 40 % tetrabutylammonium hydroxide solution and 2.2 g of disodium hydrogen phosphate in water to 780 mL, adjust pH to 7.8 with phosphoric acid) = 22:78
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 40 °C
- Detector wavelength: 280 nm

### Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC\WR154N\011-0701



The chromatogram of the test solution --- HPLC\WR154N\012-0801

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Calcium Folate	8.29	3434.7	2235	/	1.00

# Calcium Folate for Injection – 注射用亚叶酸钙

Calcium Folate – Method number WR155

## Assay

Test solution: Dissolve a quantity in water to produce a solution of 1 mg/mL, filter and use the filtrate as the test solution.

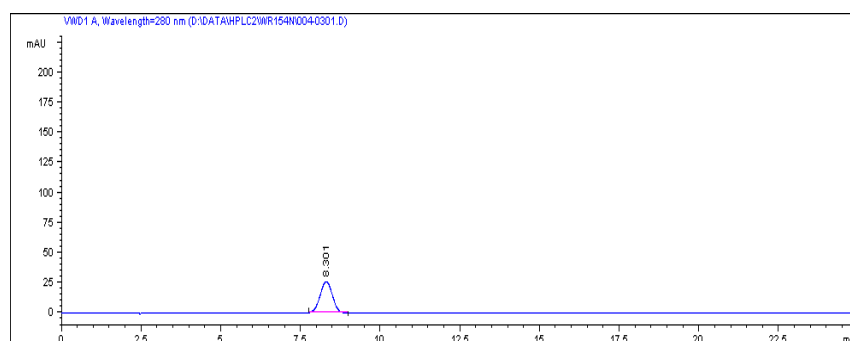
Reference solution: Dilute an accurately measured quantity of the test solution to produce the reference solution containing 10 µg/mL.

## Chromatographic conditions

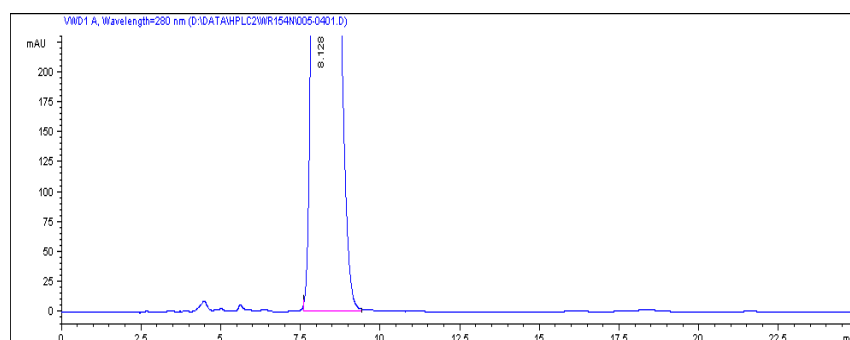
- Column: Agilent ZORBAX XDB-C18 4.6×250 mm, 5 µm (990967-902)
- Mobile phase: methanol : sodium dihydrogen phosphate BS containing 0.1 % tetrabutylammonium hydroxide solution (dissolve 2.0 mL of 40 % tetrabutylammonium hydroxide solution and 2.2 g of disodium hydrogen phosphate in water to 780 mL, adjust pH to 7.8 with phosphoric acid) = 22:78
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 40 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC2\WR154N\006-0501



The chromatogram of the test solution--- HPLC2\ WR154N \007-0601

Constituents (Test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>f</sub>
Calcium Folate	8.13	67314.5	1523	/	1.53

# Norvancomycin Hydrochloride for Injection

Norvancomycin hydrochloride (3389302) – Method number WR179

注射用盐酸去甲万古霉素

## Assay

Test solution: Dissolve a quantity of the contents in mobile phase and dilute to produce the test solution containing 1 mg/mL.

Reference solution: Dissolve a quantity of norvancomycin hydrochloride CRS in water and dilute to produce the reference solution containing 1 mg/mL.

### • Mobile phase:

A: acetonitrile : tetrahydrofuran : triethylamine solution (mix 6 mL of triethylamine and 2000 mL of water, adjust pH to 3.2 with phosphoric acid) = 3:1:96

B: acetonitrile : tetrahydrofuran : triethylamine solution (mix 6 mL of triethylamine and 2000 mL of water, and adjust pH to 3.2 with phosphoric acid) = 29:1:70

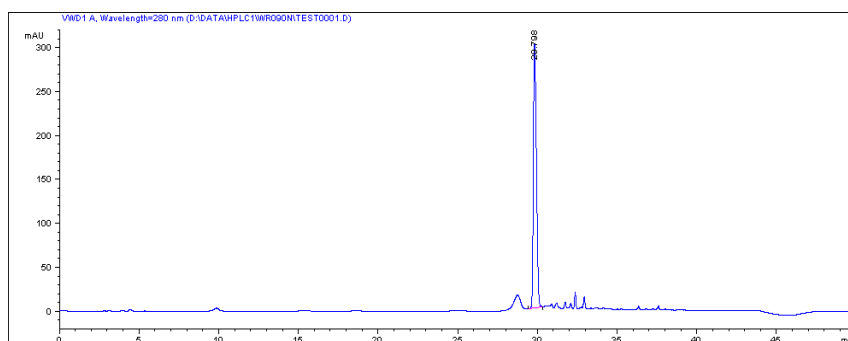
Gradient: 0 min, 100 %A;  
23 min, 100 %A; 38 min, 0 %A;  
40 min, 0 %A; 41 min, 100 %A;  
50 min, 100 %A

## Chromatographic conditions

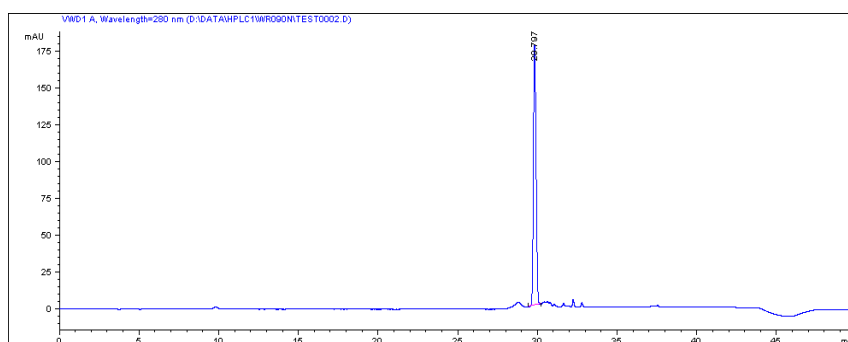
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: see assay
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution ---HPLC1\WR090N\TEST0001



The chromatogram of the test solution --- HPLC1\WR090N\TEST0002

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Norvancomycin Hydrochloride	29.80	2056.9	147188	/	1.17

# Norvancomycin Hydrochloride for Injection

Norvancomycin hydrochloride (3389302) – Method number WR179

注射用盐酸去甲万古霉素

## Assay

Test solution: Dissolve a quantity in water and dilute to produce the test solution of 2 mg/mL.

Reference solution: Dissolve a quantity in water and dilute to produce the reference solution of 20 µg/mL.

### • Mobile phase:

A: acetonitrile : tetrahydrofuran : triethylamine solution (mix 6 mL of triethylamine and 2000 mL of water, and adjust pH to 3.2 with phosphoric acid) = 3:1:96

B: acetonitrile : tetrahydrofuran : triethylamine solution (mix 6 mL of triethylamine and 2000 mL of water, and adjust pH to 3.2 with phosphoric acid) = 29:1:70

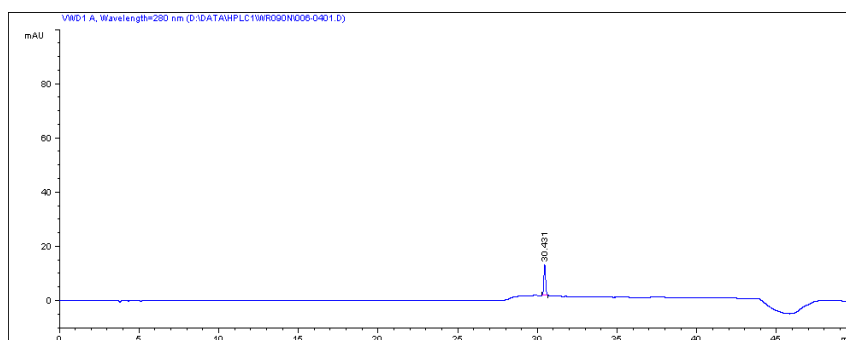
Gradient: 0 min, 100 %A;  
23 min, 100 %A; 38 min, 0 %A;  
40 min, 0 %A; 41 min, 100 %A;  
50 min, 100 %A

## Chromatographic conditions

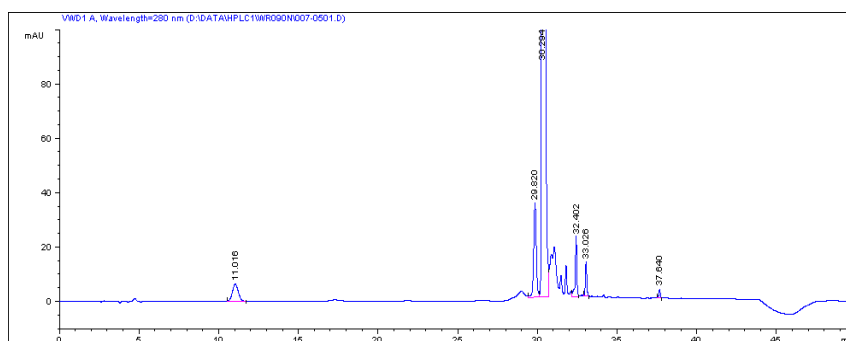
- Column: Agilent ZORBAX SB-Aq 4.6×250 mm, 5 µm (880975-914)
- Mobile phase: see assay
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Column temperature: 30 °C
- Detector wavelength: 280 nm

## Chromatographic system

- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



The chromatogram of the reference solution---HPLC1\WR090N\006-0401



The chromatogram of the test solution--- HPLC1\WR090N\ 007-0501

Constituents (test solution)	Ret Time (min)	Area (mAU*s)	N	Rs	USP T <sub>r</sub>
Impurity	29.82	400.5	174034	/	1.08
Norvancomycin Hydrochloride	30.29	8729.4	183110	1.7	/



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