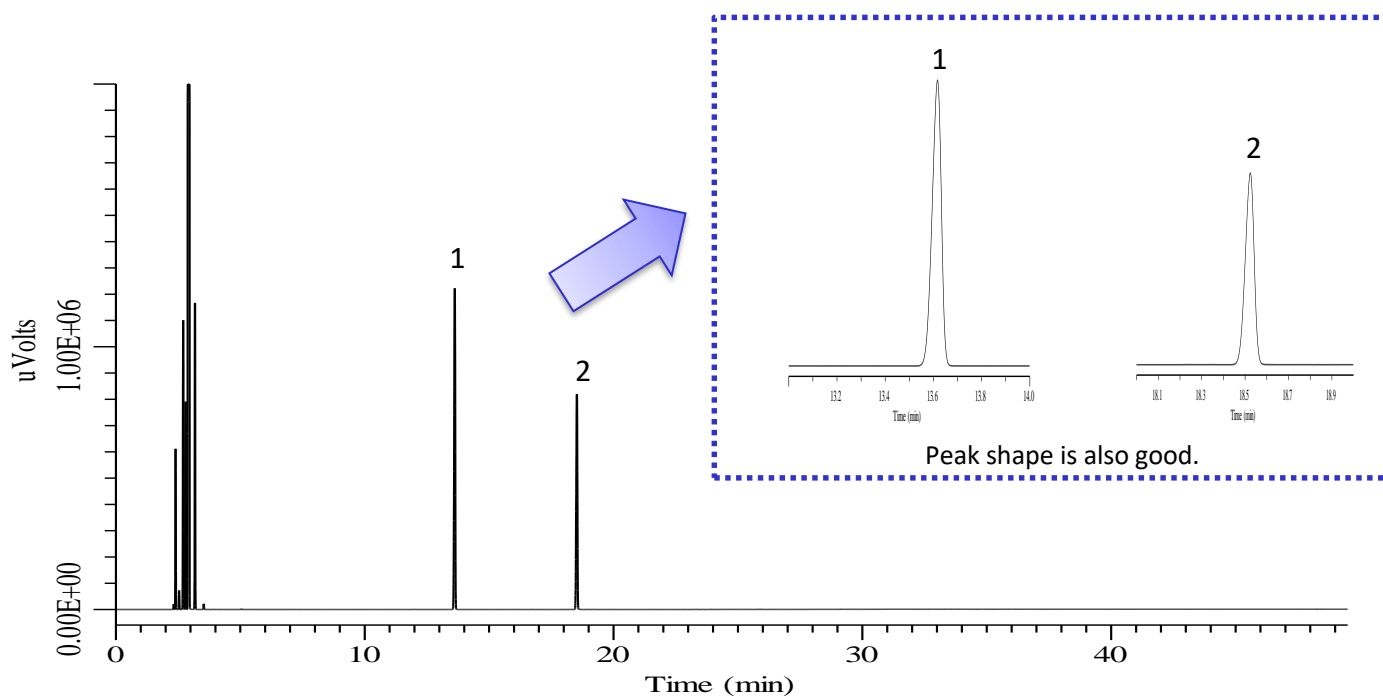


Analysis of memantine hydrochloride in accordance with the USP

Memantine hydrochloride is used to treat moderate to severe dementia (Alzheimer's type). In this application note analysis was made in accordance with the United States Pharmacopeia (USP 39). An InertCap 5 capillary column was used to analyze organic impurities, the results showed excellent resolution and reproducibility.

Analysis



Analytical conditions

Conditions

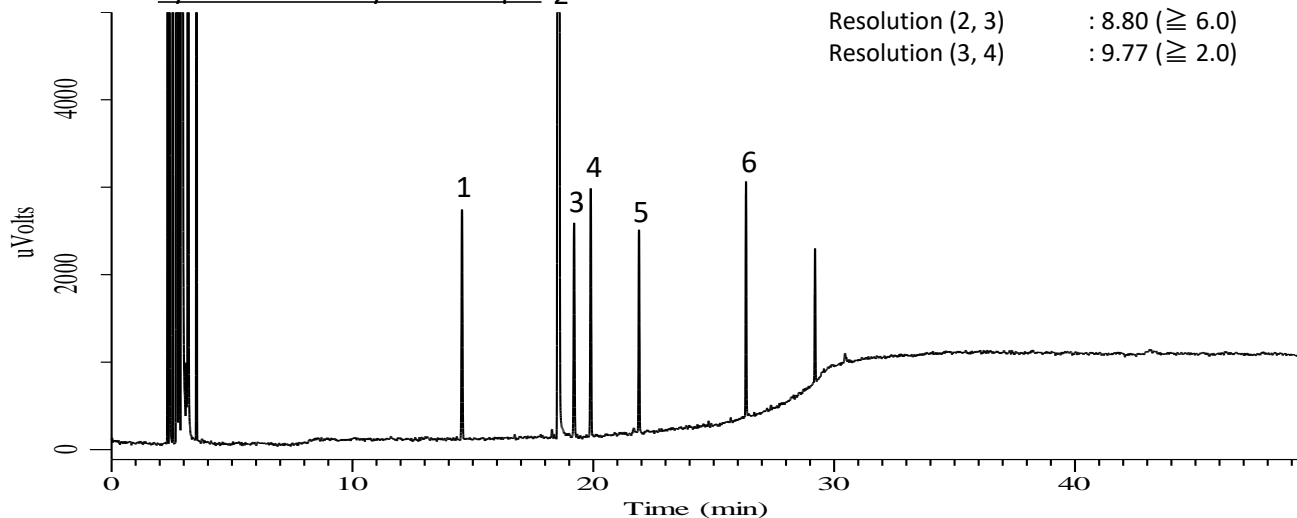
System	: GC - FID
Column	: InertCap 5 0.32 mm I.D. x 50 m df = 0.52 μ m
Col.Cat.No.	: Custom made
Col. Temp.	: 50 °C - 5 °C/min - 145 °C - 10 °C/min - 250 °C (20 min)
Carrier Gas	: He 4.0 mL/min
Injection	: Split 50:1 220 °C
Injection Vol.	: 1 μ L
Detection	: FID Auto Range 300 °C
Sample	: Standard

Analyte

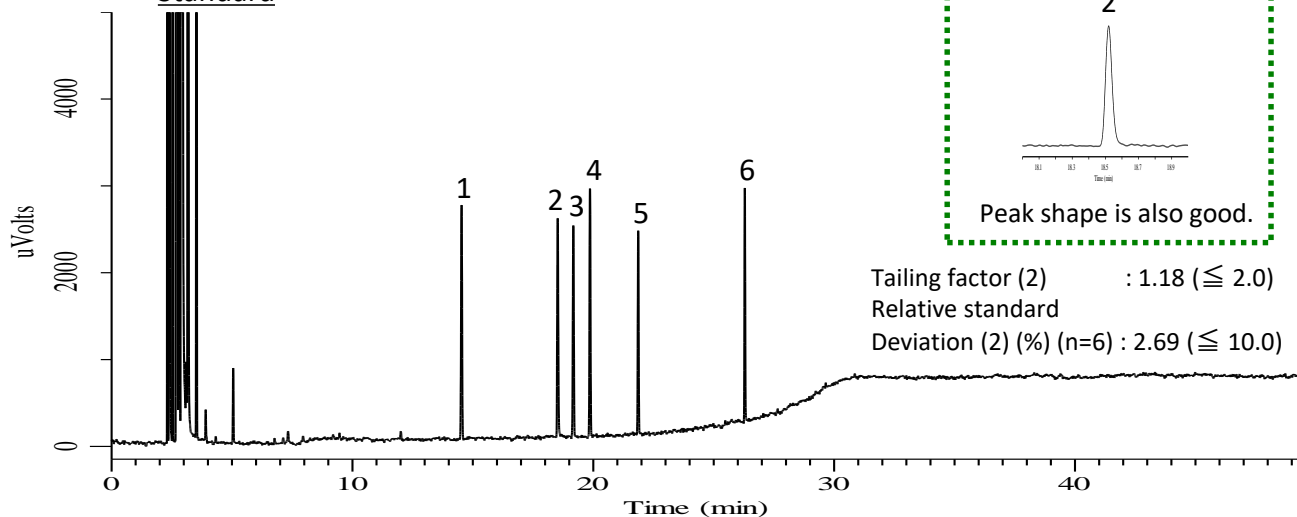
1. Adamantane	
2. Memantine	
Tailing factor (1)	: 0.85 (\leq 2.0)
Tailing factor (2)	: 0.89 (\leq 2.0)
Relative standard Deviation (1 to 2) (%) ($n=5$)	: 0.39 (\leq 2.0)

Organic Impurities

System suitability test sample 2



Standard



Analytical conditions

Conditions

System	: GC - FID
Column	: InertCap 5 0.32 mm I.D. x 50 m df = 0.52 μ m
Col.Cat.No.	: Custom made
Col. Temp.	: 50 °C - 5 °C/min - 145 °C - 10 °C/min - 250 °C (20 min)
Carrier Gas	: He 4.0 mL/min
Injection	: Split 50:1 220 °C
Injection Vol.	: 1 μ L
Detection	: FID Auto Range 300 °C
Sample	: Standard

Analyte

1. Memantine related compound A
(1,3-Dimethyladamantane)
2. Memantine
3. Memantine related compound B
(3,5-Dimethyladamantane-1-ol)
4. Memantine related compound C
(1-Chloro-3,5-dimethyladamantane)
5. Memantine related compound D
(1-Bromo-3,5-dimethyladamantane)
6. Memantine related compound E
(N-3,5-Dimethyladamantan-1-yl formamide)

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