

Assay Analysis for Penicillin G Sodium (USP-38 method):

SAMPLE PREPARATION:

Resolution Solution: Prepare a solution in water containing about 0.1 mg each of Penicillin G Potassium and 2-phenylacetamide.

Standard solution: Transfer 5mg of Penicillin G potassium to 50 ml volumetric flask, dissolve in 45 ml water and make up volume to 50ml with water.

Assay solution: Transfer 5mg of Penicillin G sodium to 50 ml volumetric flask, dissolve in 45 ml water and make up volume to 50ml with water.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC

Column: Synchronis aQ (4.6*100 mm, 5um, p/n: 97305-104630, lot no.: 12900)

Mobile phase: Prepare a mixture of 0.01M monobasic potassium phosphate and methanol (60:40). Make adjustment if necessary.

Separation Mode: Isocratic

Column temperature: 25°C

Flow rate: 1.0 mL/min

Injection Volume: 10 µl

Detector wavelength: UV 220 nm

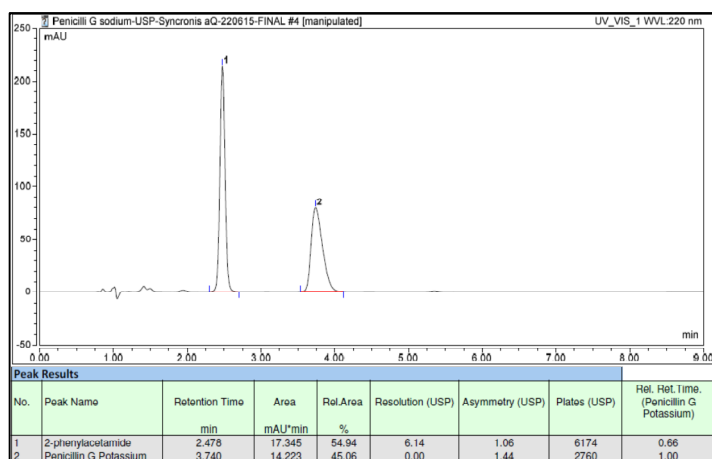
Run Time: 15min.

System Suitability Results:

Sr. No.	Parameters	USP Criteria	Obtained Results
1	Resolution between 2-phenylacetamide and Penicillin G potassium	NLT 2.0	6.14
2	Tailing factor for Penicillin G Potassium peak in standard solution	NMT 2.0	1.5
3	%RSD for replicate injection of standard solution	NMT 2.0%	0.2%
4	RRT of 2-phenylacetamide peak wrt Penicillin G potassium peak	About 0.8	0.7

CHROMATOGRAMS:

Resolution Solution:



Standard Solution:

