

Impurities test for Sulfadiazine (EP-8.0 method):

SAMPLE PREPARATION:

Solvent Mixture: 40 g/L solution of Sodium Hydroxide, Acetonitrile, Water (2:20:60 v/v/v)

Test Solution: Dissolve 50 mg of Sulfadiazine in solvent mixture and dilute to 100ml with water.

Reference solution (a): Dissolve 5mg of Impurity-A and 5 mg of impurity-B in solvent mixture and dilute to 10ml with water, dilute 1ml of solution to 100ml with mobile phase, dilute 3 ml of solution to 10 ml with mobile phase

Reference solution (b): Dilute 1ml of test solution to 100ml with mobile phase, dilute 1ml of this solution to 10 ml with mobile phase.

Reference solution-(c): Dissolve content of Impurity E CRS in 1 ml of mobile phase.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC

Column: Acclaim Polar Advantage-II C18-120 (4.6*250mm, 5um, p/n 063199, lot no.: 012-05-056)

Mobile phase: Acetonitrile: 2.8 g/L solution of phosphoric acid (10:90).

Separation Mode: Isocratic

Column temperature: 25°C

Flow rate: 1.2 mL/min

Injection Volume: 20 µl

Detector wavelength: UV260 nm

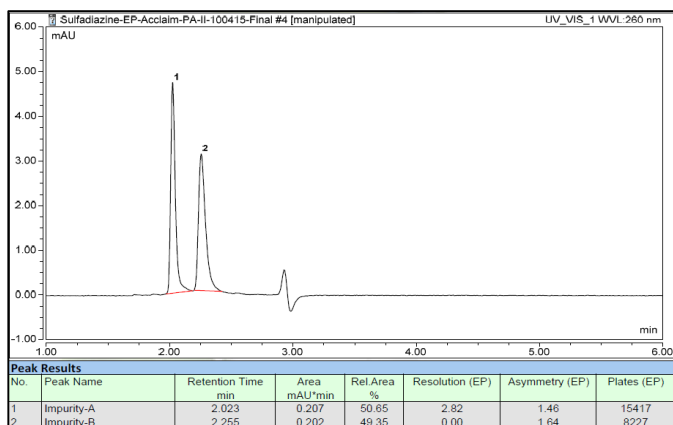
Run Time: 35min

System Suitability Results:

Sr. No.	Parameters	EP Criteria	Obtained Results
1	Resolution b/w Impurity-A and Impurity-B	NLT 2.0	2.8
2	Tailing Factor for Sulfadiazine peak	NMT 2.0	0.8

CHROMATOGRAMS:

System Suitability:



Impurity Mix:

