

Impurities test for Ceftriaxone Sodium (EP-8.0 method):

SAMPLE PREPARATION:

Reference solution-(a): Dissolve 30 mg of Ceftriaxone sodium in mobile phase and dilute to 100 ml with mobile phase.

Test Solution: Dissolve 30 mg of Ceftriaxone sodium in mobile phase and dilute to 100 ml with mobile phase.

Reference solution-(b): Dissolve 5.0mg of Ceftriaxone sodium and 5.0 mg of ceftriaxone Impurity-A.

Reference solution-(c): Dilute 1.0 ml of test solution to 100 ml with mobile phase.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC

Column: Synchronis C18 (4.6*250mm, 5um, p/n: 97105-254630, lot no.: 11811)

Mobile phase: Dissolve 2gm of tetradecylammonium bromide and 2gm of tetraheptylammonium bromide in a mixture of 440 ml of water, 55ml of 0.067 phosphate buffer pH 7.0, 5 ml of citrate buffer solution pH 5.0 prepared by dissolving 20.17 gm of citric acid in 800ml water, adjusting pH to 5.0 with strong sodium hydroxide solution and diluting to 1000 ml with water and 500 ml of Acetonitrile.

Separation Mode: Isocratic

Column temperature: 25°C

Flow rate: 1.5 mL/min

Injection Volume: 20 µl

Detector wavelength: UV254 nm

Run Time: 30min

System Suitability Results:

Sr. No.	Parameters	USP Criteria	Obtained Results
1	Resolution between Ceftriaxone sodium and Impurity-A (Ceftriaxone sodium E isomer)	Minimum 3.0	9.99

CHROMATOGRAMS:

System Suitability:

