

Impurities test for Ofloxacin (EP-8.0 method):

SAMPLE PREPARATION:

Solvent Mixture: Acetonitrile:Water (10:60 v/v)

Test Solution: Dissolve 10 mg of Ofloxacin in Solvent Mixture and dilute to 50 mL with solvent mixture.

Reference solution (a): Dilute 1mL of test solution to 50 mL with solvent mixture, dilute 1 mL of this solution to 10 mL with solvent mixture.

Reference solution (b): Dissolve 10 mg of Ofloxacin impurity E in solvent mixture, add dilute to 100 mL with solvent mixture, Mix 10 mL of the solution and 5 mL of test solution and dilute to 50 mL with solvent mixture. Dilute 1 mL of this solution to 50 mL with solvent mixture.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC

Column: Synchronis C18 (4.6*150mm, 5um, p/n 97105-154630, lot no.: 11811).

Mobile phase: Dissolve 4 g of ammonium acetate and 7 g of sodium perchlorate in 1300 ml of water, adjust to pH 2.2 with phosphoric acid and add 240 ml of Acetonitrile.

Separation Mode: Isocratic

Column temperature: 45°C

Flow rate: 0.5 mL/min

Injection Volume: 10 µL

Detector wavelength: 294 nm

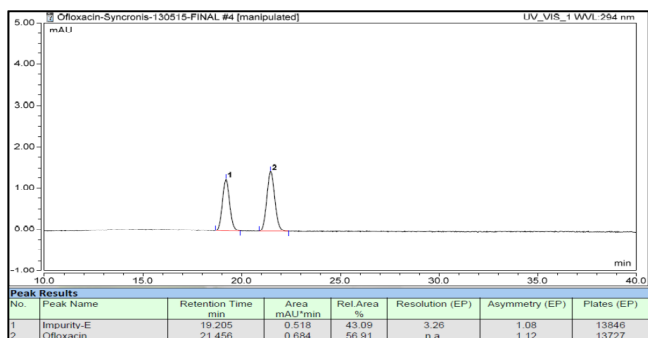
Run Time: 50 min

System Suitability Results:

Sr. No.	Parameters	EP Criteria	Obtained Results
1	Resolution b/w Impurity E and Ofloxacin Peak	NLT 2.0	3.26

CHROMATOGRAMS:

System Suitability:



Impurity Mix:

