

## 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:** Syncronis 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

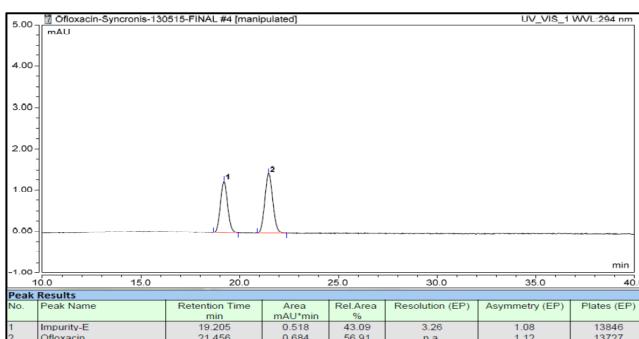
**Run Time:** 50 min

### **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:**

