# Impurities test for Levofloxacin (USP-38 method):

## SAMPLE PREPARATION:

**System Suitability Solution:** 1 mg/ml of Levofloxacin in Mobile Phase.

**Sensitivity solution:** 0.3 µg/ml of Levofloxacin in Mobile Phase.

**Sample solution:** 1 mg/ml of Levofloxacin in Mobile Phase.

## CHROMATOGRAPHIC CONDITIONS:

**Instrument:** UltiMate 3000 LC
**Column:** Acclaim 120-C18 (4.6*250mm, 5um, p/059149, lot no.: 018-01-152)

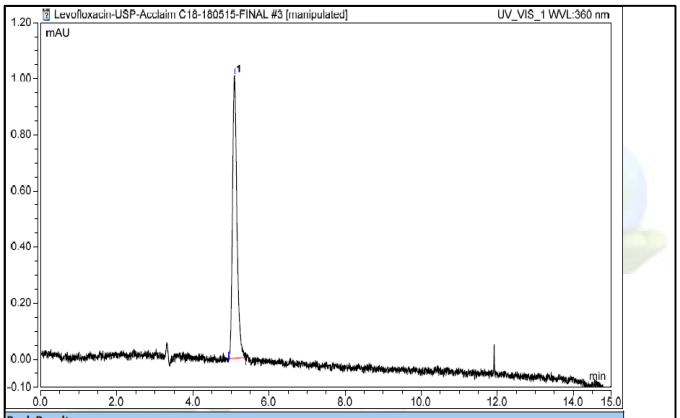
**Buffer**: 8.5gm/lt of ammonium acetate, 1.25 gm/lt of cupric sulphate pentahydrate and 1.3gm/lt of L-Isoleucine in water
**Mobile phase:** 3:7 (Methanol: Buffer).
**Separation Mode: Isocratic**
**Column temperature:** 45˚C
**Flow rate:** 0.8 mL/min
**Injection Volume:** 25 µl
**Detector wavelength:** UV 360 nm
**Run Time:** 15min

### System Suitability Results:

| Sr. No. | Parameters | USP Criteria | Obtained Results |
|---|---|---|---|
| 1 | Relative standard deviation for System suitability solution | NMT 1.0% | 0.06% |
| 2 | Signal to noise ratio for sensitivity solution | NLT 10 | 58.4 |

## CHROMATOGRAMS:

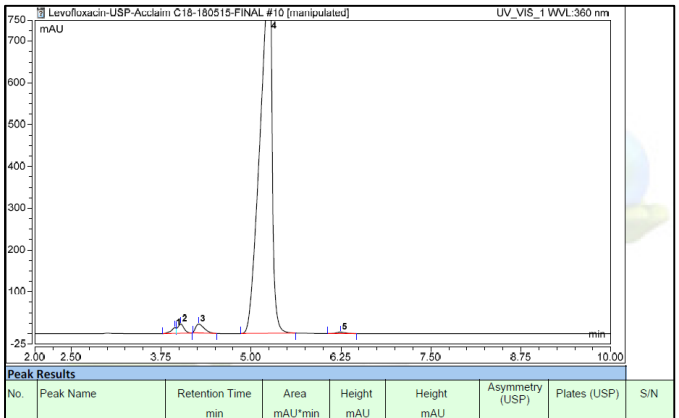
**Sensitivity Solution:**




Peak Results

| No. | Peak Name | Retention Time min | Area mAU*min | Height mAU | Height mAU | Asymmetry (USP) | Plates (USP) | S/N |
|---|---|---|---|---|---|---|---|---|
| 1 | Levofloxacin | 5.095 | 0.136 | 1.010 | 1.010 | 1.25 | 10172 | 58.4 |

**Impurity Mix:**




Peak Results

| No. | Peak Name | Retention Time min | Area mAU*min | Height mAU | Height mAU | Asymmetry (USP) | Plates (USP) | S/N |
|---|---|---|---|---|---|---|---|---|
| 1 | Impurity-A | 3.938 | 1.103 | 13.764 | 13.764 | n.a. | 3810 | 7.3 |
| 2 | Impurity-E | 4.023 | 2.225 | 22.535 | 22.535 | n.a. | 8861 | 12.0 |
| 3 | Impurity-D | 4.273 | 2.910 | 21.359 | 21.359 | 1.69 | 5844 | 11.4 |
| 4 | Levofloxacin | 5.260 | 172.694 | 955.545 | 955.545 | 0.68 | 4646 | 508.4 |
| 5 | Impurity-C | 6.245 | 0.504 | 3.463 | 3.463 | 1.19 | 11991 | 1.8 |