Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical profile of Moxifloxacin Hydrochloride Infusion

Analytical Profile No.: Moxiflo 079/080/AP 124

Moxifloxacin Hydrochloride Infusion contains not less than 90.0% and not more than 110.0% of the stated amount of Moxifloxacin.

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. pH: As per manufacturer's specification

3. Particulate Matter: As per IP latest edition

4. Sterility: As per IP latest edition

5. Bacterial Endotoxin Test: As per IP latest edition

Limit: NMT 0.8 EU/mg

6. Assay: *Determine by liquid chromatography*

6.1 Diluent: Water: Acetonitrile: Methanol (50:25:25)

6.2 Test solution: Transfer 10 ml of sample solution equivalent to 40 mg of moxifloxacin into 50 ml of volumetric flask, add about 30 ml of diluent, sonicate, cool to room temperature and make up the volume with diluent. Further dilute 5 ml of this solution to 50 ml with diluent and mix.

6.3 Reference solution: Weigh accurately about 40 mg of Moxifloxacin WS and transfer into 50 ml volumetric flask (amber colored), add about 30 ml of diluent, sonicate, cool to room temperature and make up the volume with diluent. Further dilute 5 ml of this solution to 50 ml with diluent and mix.

6.4 Chromatographic system:

- **Column:** C18, (250 x 4.6) mm, 5 µm particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 240 nm
- **Injection volume:** 20 µl
- **Detector:** UV

- **Column temperature:** 45°C

- **Mobile Phase:** A mixture of 50 volumes of Buffer, 25 volumes of Acetonitrile, 25 volumes of Methanol and 0.1volume of Methane sulphonic acid

    - **Buffer:** Dissolve 7. 6012 gm of tri-sodium orthophosphate 12-hydrate in 1000 ml of water. Adjust pH to 3.0 ± 0.1 with Orthophosphoric acid

6.5 Procedure:

Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Moxifloxacin in Moxifloxacin Hydrochloride Infusion.

6. Other tests: As per pharmacopoeial requirement.