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

Analytical profile of Moxifloxacin Eye Ointment

Analytical Profile No.: Moxif 076/077/AP 068

Moxifloxacin Eye Ointment contains not less than 95.0% 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. Sterility: As per IP (latest edition)

3. Particle Size: As per IP (latest edition)

6. Assay: *Determine by Liquid Chromatography*

6.1 Test Solution: Weigh ointment equivalent to 50mg of Moxifloxacin in a separating flask, add about 40ml of cyclohexane and extract with 4 x 20ml of mobile phase, collect the mobile phase in a 100ml volumetric flask. Dilute up to the mark to 100ml with mobile phase. Further dilute 1ml of this solution to 10ml with mobile phase.

6.2 Reference Solution: Weigh accurately about 50 mg of *Moxifloxacin WS* in a 100 ml volumetric flask. Add about 70ml of mobile phase, sonicate to dissolve and make up the volume with mobile phase. Further dilute 1ml of this solution to 10ml with mobile phase.

6.3 Chromatographic system

- **Column:** C18, (250 x 4.6 mm) 5 µm
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 254 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Mobile phase:** 0.01M KH_2PO_4: Methanol (30:70)

6.4 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; the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0%. Measure the peak response. Calculate the content of Moxifloxacin in eye ointment.

7. Other tests: As per pharmacopoeial requirement.