DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Moxifloxacin Eye Ointment

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

Moxifloxacin Eye Ointment contains not less than 90 % and not more than 110 % 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.

Tests:

2. Sterility: As per IP (latest edition)

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

4. Assay: Determine by Liquid Chromatography

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

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

4.3 Chromatographic system

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

4.4 Procedure: Inject the reference solution five times and test solution. 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 %.

Calculate the content of Moxifloxacin in eye ointment.

5. Other tests: As per pharmacopoeial requirement.