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

Ciprofloxacin Hydrochloride Powder

Analytical Profile No.: Ciprovet 081/082/AP 169

Ciprofloxacin Hydrochloride Powder contain not less than 90.0% and not more than 110.0% of the stated amount of Ciprofloxacin.

Usual Strength: 20% w/w

1. Identification:

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

2. Assay: *Determine by liquid chromatography*

2.1 Solution A: 0.025 M phosphoric acid. Adjust with triethylamine to a pH of 2.0 ± 0.1.

2.2 Solution B: Acetonitrile and Solution A (13:87)

2.3 Solution C: 0.025 M phosphoric acid. Adjust with triethylamine to a pH of 3.0 ± 0.1.

2.4 Test solution: Weigh the quantity of the powder containing 200 mg of Ciprofloxacin in a 100 ml dry volumetric flask, add 60 ml of solution B, and sonicate for 10 minutes to dissolve. Cool the sample solution to room temperature make up the volume with the same solvent and mix. Dilute 5 ml of the resulting solution to 50 ml with same solvent.

2.5 Reference solution: Weigh accurately about 20.0 mg of Ciprofloxacin Hydrochloride WS and transfer to a 100 ml completely dried volumetric flask. Dissolve in 60 ml of solution B with the aid of ultrasound and make up the volume with the same solvent.

2.6 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µm)

Wavelength: 278 nm

Injection volume: 10 µl

Flow Rate: 1.5 ml/minute

Column Temperature: 30ºC

Mobile phase: Acetonitrile and Solution C (13:87)

2.7 Procedure: Inject the reference solution five times and test the 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 is not more than 1.5%. Measure the peak responses. Calculate the content of Ciprofloxacin in the powder.

3. Other tests: As per Pharmacopoeial requirements.