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

Analytical profile of Ciprofloxacin Oral Solution (Veterinary)

Analytical Profile No.: Cipro 080/81/AP 150

Ciprofloxacin Oral Solution contains not less than 90.0% and not more than 110.0% of the stated amount of Ciprofloxacin.

Usual Strength: 10% w/v solution

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. Assay: *Determine by liquid chromatography*

3.1 Test solution: Weigh and transfer sample equivalent to 100 mg of Ciprofloxacin (1 ml sample) in 200 ml volumetric flask, add 50 ml of water, sonicate for 5 minutes. Make up the volume with water, mix and filter the solution through suitable filter. Dilute 10 ml of above filtrate to 20 ml with water.

3.2 Reference solution: Weigh accurately 55.5 mg of Ciprofloxacin HCl WS and transfer in 100 ml completely dried volumetric flask, dissolve and dilute to volume with water and mix. Dilute 10 ml of the solution to 20 ml with water.

3.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.5 ml/min

Wavelength: 278 nm

Injection volume: 10 µl

Column Temperature: 30ºC

Mobile Phase: A mixture of 87 volumes of 0.025M phosphoric acid, previously adjusted pH to 3.0±0.1 with triethylamine and 13 volumes of acetonitrile.

3.4 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, 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 Ciprofloxacin in Ciprofloxacin Oral Solution

4. Other tests: As per Pharmacopoeial requirements.