ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT
DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory

Levofloxacin Oral Solution (vet)

Analytical Profile No.: Levo V 077/078/AP 081

Levofloxacin Oral Solution (Vet.) contains not less than 90% and not more than 110% of the stated amount of Levofloxacin.

1. Identification:

In the assay, the peak maxima in the spectrum obtained with the test solution should correspond to the peak maxima in the spectrum obtained with the reference solution of Levofloxacin.

2. pH: As per manufacturer's specification

3. wt/ml: As per manufacturer's specification

4. Assay: *Determine by UV-Vis spectrophotometer*

4.1 Test solution: Shake well and weigh sample equivalent to 50 mg of Levofloxacin Hemihydrate and transfer into 100 ml volumetric flask. Add about 70 ml of 0.1M HCl, sonicate for about 10-15 minutes, cool at room temperature and make up the volume to 100 ml with same solvent. Dilute 1 ml of the resulting solution to 100 ml with same solvent.

4.2 Reference solution: Weigh accurately about 50 mg of Levofloxacin Hemihydrate WS and transfer into 100 ml volumetric flask. Dissolve with 0.1M HCl and make up the volume to 100 ml with same solvent. Dilute 1 ml of the resulting solution to 100 ml with same solvent.

4.3 Procedure: Measure the absorbance of the reference and test solution at the maximum at 293 nm using 0.1M HCl as blank.

Calculate the content of Levofloxacin in the solution.

5. Other tests: As per pharmacopoeial requirements.