

DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Enrofloxacin Oral Solution (Vet)

Analytical Profile No.: Enrof 076/077/AP 067

Enrofloxacin Oral Solution contains not less than 90 % and not more than 110 % of the stated amount of Enrofloxacin.

1. Identification: The solution prepared for the assay exhibits maxima at 277 nm and its spectrum is concordant with the spectrum of reference solution.

Tests:

2. pH: 10.5 to 12.5

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

4. Assay:

4.1 Test Solution: Weigh the sample equivalent to 50 mg of Enrofloxacin in 100 ml volumetric flask, dissolve it in 0.1 M HCl and make up the volume with same solvent. Dilute 1 ml of resulting solution to 100 ml with same solvent.

4.2 Reference Solution: Weigh accurately about 50 mg of Enrofloxacin reference standard in a 100 ml volumetric flask, dissolve it in 0.1 M HCl and make up the volume with same solvent. Dilute 1 ml of resulting solution to 100 ml with same solvent.

4.3 Procedure: Measure the absorbance of both reference and test solution in UV-Vis Spectrophotometer at a wavelength of 277 nm against 0.1 M HCl as blank. Calculate the content of Enrofloxacin in the solution.

5. Other tests: As per pharmacopoeial requirement.