DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Mefenamic Acid Oral Suspension

Analytical profile no.: Mefe 077/078/AP 095

Mefenamic acid oral suspension contains not less than 90.0% and not more than 110.0% of the stated amount of Mefenamic acid.
Usual Strength: Each 5ml contains Mefenamic acid 50 mg

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. pH: As per manufacturer's specification

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

4. Assay: *Determine by liquid chromatography*

4.1 Test solution: Shake well and weigh accurately about the sample equivalent to 50 mg of MefenamicAcid (5 x weight per ml of suspension) in 50ml of volumetric flask, add 25ml of mobile phase and sonicate. Cool to room temperature and make up the volume with same solvent up to the mark and stir mechanically for 30 minutes. Filter through whatman filter paper. Further dilute 10ml of this solution to 50ml with same solvent. Mix well and filter through 0.2 micron filter paper.

4.2 Reference solution: Weigh accurately about 50mg of mefenamic Acid WS and transfer it to the 50ml volumetric flask. Add about 30 ml of mobile phase and sonicate, cool to room temperature and make up the volume with same solvent up to mark. Further dilute 10ml of this solution to 50ml with same solvent. Mix well and filter through 0.2 micron filter paper.

4.3 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.5 ml/min
- **Wavelength:** 254 nm
- **Injection volume:** 20 µl
- **Detector:** UV

- **Column temperature:** 30 °C

- **Mobile Phase:** A mixture of 40 volumes of buffer, 46 volumes of Acetonitrile and 14 volumes of tetrahydrofuran

- **Buffer:** Prepare 0.05M of Ammonium dihydrogen phosphate in water.AdjustPh 5.0 with 3M Ammonia

4.4 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 Mefenamic acid in the suspension.

5. Other tests: As per pharmacopoeial requirement.