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

Analytical profile of Metronidazole & Diloxanide Furoate Suspension

Analytical Profile No.: Metr Dilo L 076/077/AP 069

Metronidazole & Diloxanide Furoate Suspension contains not less than 90.0% and not more than 110.0% of the stated amount of Metronidazole & Diloxanide Furoate.

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: Weigh accurately about sample in gm equivalent to 100mg of Metronidazole & 125mg of Diloxanide Furoate in 100ml volumetric flask, make up the volume with mobile phase up to the mark and stir mechanically for 30 minutes. Further dilute 5ml of this solution to 50ml with same solvent, mix well.

4.2 Reference Solution: Weigh accurately about 80.4 mg Metronidazole Benzoate WS and 62.5 mg of Diloxanide Furoate WS in a 50 ml volumetric flask, add about 30ml of mobile phase and sonicate for about 15 minutes; cool to room temperature and make up the volume with same solvent. Further dilute 5ml of this solution to 50ml with same solvent, mix well.

4.3 Chromatographic system

- **Column:** C 18, (250 x 4.6 mm) 5 µm
- **Flow rate:** 1.0 ml/min
- **wavelength:** 241 nm
- **Injection volume:** 10 µl
- **Detector:** UV
- **Column Temperature:** 30 ºC

- **Mobile phase:** A mixture of 30 volumes of Buffer, 30 volumes of Acetonitrile & 40 volumes of Methanol.

  Buffer: prepared by dissolving 1.625gm of Potassium dihydrogen phosphate and 0.3gm of Dipotassium hydrogen phosphate in 1000ml of water, adjusting pH to 5.5 with orthophosphoric acid.

4.4 Procedures: Inject the reference solution. 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, the relative standard deviation for replicate injections in not more than 2.0% and the resolution between Metronidazole & Diloxanide Furoate is not less than 2. Measure the peak response. Calculate the content of Metronidazole & Diloxanide Furoate in the suspension.

5. Other tests: As per pharmacopoeial requirement.