DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Florfenicol Oral Solution

Analytical profile no.: Flor 077/078/AP 089

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

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 of Florfenicol..

Tests:

2. pH: As per manufacturer's specification

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

4. Total aerobic viable count: As per Indian Pharmacopoeia (latest edition)

5. Total Fungal Count: As per Indian Pharmacopoeia (latest edition)

6. Test for specific microorganism (E. Coli): As per Indian Pharmacopoeia (latest edition)

7. Assay: *Determine by liquid chromatography*

7.1 Test solution: Shake well and weigh sample equivalent to 25 mg of Florfenicol and transfer into 50 ml volumetric flask. Add about 30 ml of methanol, and sonicate, cool at room temperature and make up the volume to 50 ml with same solvent.

7.2 Reference solution: Weigh accurately about 25 mg of Florfenicol WS and transfer into 50 ml volumetric flask. Dissolve with methanol and make up the volume to 50 ml with same solvent.

7.3 Chromatographic system:

- **Column:** C18(2) 100A, (250 x 4.6 mm), 5 µ particle size; Phenomenex Luna
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 223 nm
- **Injection volume:** 10 µl
- **Detector:** UV
- **Column temperature:** 30 °C

- **Mobile Phase:** A mixture of 240 volumes of Acetonitrile and 760 volumes of water

7.4 Procedure: Inject the reference solution five/six 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 Florfenicol in the solution.

8. Other tests: As per pharmacopoeial requirement.