Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical Profile of Florfenicol Powder for Oral Solution

Analytical Profile No.: Florfenicol 082/083 AP 181

Florfenicol Powder contains not less than 90.0% and not more than 110.0% of the stated amount of Florfenicol.

Usual Strength: Each gram contains: Florfenicol 300 mg

1. Identification:

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. Assay: *Determine by liquid chromatography*

2.1 Test solution: Shake well and weigh sample equivalent to 25 mg 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.

2.2 Reference solution: Weigh accurately about 25.0 mg of Florfenicol WS and transfer to a 50 ml volumetric flask. Dissolve with methanol and make up the volume to 50 ml with the same solvent.

2.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µm)

Wavelength: 223 nm

Injection volume: 10 µl

Flow Rate: 1 ml/minute

Column Temperature: 30ºC

Mobile phase: Acetonitrile: Water (24:76)

2.4 Procedure: Inject the reference solution five times and test the solutions. 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, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Florfenicol

3. Other tests: As per Pharmacopoeial requirements.