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

Analytical profile of Levodropropizine Syrup

Analytical Profile No.: Levodro 080/81/AP 141

Levodropropizine Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Levodropropizine.

Usual Strength: 30 mg per 5 ml

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: Pipette 5 ml of syrup to a 100 ml volumetric flask. Dilute with mobile phase to volume and mix.

4.2 Reference solution: Dissolve accurately weighed about 30 mg of Levodropropizine working standard in mobile phase to a 100 ml volumetric solution. Dilute with mobile phase to volume and mix.

4.3 Chromatographic system:

Column: C18 (4.6 mm X 250 mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 242 nm

Injection volume: 20µl

Column Temperature: 25ºC

Mobile Phase: Prepare a filtered and degassed mixture of methanol, water and triethylamine in a ratio of 30:70:5. Adjust with glacial acetic acid to a pH of 6.5.

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 Levodropropizine in Levodropropizine Syrup.

5. Other tests: As per pharmacopoeial requirements.