DEPARTMENT OF DRUG ADMINISTRATION

National Medicines Laboratory

ANALYTICAL METHOD VALIDATION COMMITTEE

Levodropropionate & Chlorpheniramine Maleate Syrup

Analytical Profile No.: Levo Chlor 078/079/AP 101

Levodropropionate & Chlorpheniramine Maleate Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Levodropropionate & Chlorpheniramine Maleate.

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. Microbial Limit Test: As per IP latest edition

5. Absence of specified Microorganism: As per IP latest edition

6. Assay: *Determine by liquid chromatography*

6.1 Diluent: 0.1 N Hydrochloric Acid

6.2 Test solution: Weigh about 5g of sample and transfer into 50 ml volumetric flask. Add about 30 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume to 50 ml with same solvent. Dilute 2 ml of the solution to 25 ml with mobile phase.

6.3 Reference solution:

Levodropropizine Standard: Weigh accurately about 50 mg of Levodropropizine WS and transfer into 100 ml volumetric flask. Add about 70 ml of diluent, and sonicate to dissolve, cool to room temperature and make up the volume to 100 ml with same solvent.

Chlorpheniramine Maleate Standard: Weigh accurately about 50 mg of Chlorpheniramine Maleate WS and transfer into 50 ml volumetric flask. Add about 30 ml of diluent, and sonicate to dissolve, cool to room temperature and make up the volume to 50 ml with same solvent. Dilute 2 ml of the solution to 25 ml with mobile phase.

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Composite Standard: Dilute 2 ml of Levodropropizine Standard and 1 ml of Chlorpheniramine Maleate Standard to 25 ml with mobile phase.

6.4 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.5 ml/min
- **Wavelength:** 215 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Column temperature:** 30 °C
- **Mobile Phase:** A mixture of 93 volumes of 0.05M Phosphate buffer and 7 volumes of Acetonitrile

    -**0.05 M Phosphate Buffer:** Dissolve 6.805 gm of Potasium dihydrogen orthophosphate in 1000ml of water.

6.5 Procedure: Inject the reference solution five times. 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%. Inject the test solution. Measure the peak responses. Calculate the content of Levodropropizine and Chlorpheniramine Maleate in syrup.

7. Other tests: As per pharmacopoeial requirements.

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