

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

Analytical profile of Levocetirizine Dihydrochloride Syrup

Analytical Profile No.: Levc 073/074/AP 008

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

Usual strength: 2.5 mg/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.

Tests:

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 the sample equivalent to 5 mg of levocetirizine dihydrochloride and transfer into 100 ml volumetric flask. Add about 70 ml of mobile phase, sonicate for about 15 minutes, cool and make up the volume with same solvent.

4.2 Reference Solution: Weigh accurately about 25 mg of levocetirizine dihydrochloride RS and transfer in 50 ml volumetric flask. Add about 30 ml of mobile phase, sonicate for about 5 minutes, cool and make up the volume with same solvent. Dilute 5ml of the resulting solution to 50 ml with mobile phase.

4.3 Chromatographic system:

Column: (250 × 4.6) mm; 5 micron, ODS (C18)

Flow rate: 1.0 ml/ min.

Wavelength: 230 nm

Injection volume: 20 µl

Temperature: Ambient

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Mobile Phase: A mixture of 65 volume of 0.05M potassium dihydrogen phosphate adjust the pH to 6.0 with 10% w/v of sodium hydroxide and 35 volume of acetonitrile.

Procedure: Inject the reference solution five/six times and test 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 in not more than 2.0%. Measure the peak response and calculate the content of levocetirizine HCl in the syrup.

4. Other tests: As per pharmacopoeial requirement.