ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT
DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory

Levocetirizine Dihydrochloride Syrup

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

Levocetirizine Dihydrochloride Syrup contains not less than 90% and not more than 110% of Levocetirizine dihydrochloride.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Levocetirizine Dihydrochloride.

2. pH: 4 to 6

3. wt/ml: As per the 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 by sonicating for about 5 minutes, cool and make up the volume with same solvent. Filter through 0.2 micron filter paper.

4.2 Reference Solution:

Weigh accurately about 25.0 mg of of levocetirizine dihydrochloride WS and transfer in 50 ml volumetric flask. Dissolve it with 50 ml mobile phase, by sonicating 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. Filter through 0.2 micron filter paper.

4.3 Chromatographic system:

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

Flow rate : 1.0 ml/ min.

Wavelength: 230 nm

Injection volume: 20 µl

Column Temperature: Ambient

Detector: UV

Mobile Phase:

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

4.4 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. The tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0%.

Inject the reference solution and test solution.

Calculate the content of levocetirizine HCl in the syrup.

5. Other tests: As per pharmacopoeial requirement