DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

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 the stated amount of Levocetirizine dihydrochloride.

1. Identification:

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

Tests:

2. pH: 4-6

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 50 ml of mobile phase and dissolve 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 working standard of levocetirizine dihydrochloride 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 5 ml of the resulting solution to 50 ml with mobile phase. Filter through 0.2 micron filter paper. (50 ppm)

4.3 Chromatographic system:

Column: a stainless steel column 25 cm x 4.6 mm, packed with octadecyl silane bonded to porous silica (5 µm)

Flow rate: 1.0 ml per minute,

Wavelength: 230 nm

Injection volume: 20 µl

Detector: UV

Column temperature: Ambient

Mobile phase: a mixture of 65 volumes of 0.05 M potassium dihydrogen phosphate adjusted to pH 6.0 with 10 % sodium hydroxide and 35 volumes of acetonitrile.

4.4 Procedure: Inject 20 µl of reference solution five times using the above mentioned chromatographic conditions. 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 in not more than 2.0%. Inject test solution, blank solution.

Calculate the content of levocetirizine dihydrochloride. in the syrup.

5 Other tests: As per pharmacopoeial requirements.