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

Analytical profile of Montelukast and Levocetirizine Dihydrochloride Syrup

Analytical Profile No.: Monte Levocet 078/079/AP 109

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

Usual Strength: Each 5 ml contains:

Montelukast Sodium equivalent to Montelukast 4 mg

Levocetrizine Dihydrochloride 2.5 mg

1. Identification:

In the Assay, the principle peaks in the chromatogram obtained with the test solution correspond 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 Enumeration Test: As per IP latest edition

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

6. Assay:

6.1 Montelukast: *Determine by liquid chromatography*

6.1.1 Solvent Mixture: 20 volumes of water and 80 volumes of methanol

6.1.2 Test solution: Pipette 10 ml of the sample solution in 100 ml volumetric flask (amber color), add 30 ml of the solvent mixture, sonicate for 10 minutes in ice cold water. Make up the volume with same solvent, stir for 10 min, filter and use.

6.1.3 Reference solution: Weigh accurately and transfer about 41.6 mg of Montelukast sodium WS to a 100ml volumetric flask (amber color); add about 70ml of solvent mixture and sonicate

for 10 minutes in ice cold water. Make up the volume with same solvent, stir for 5 minutes. Dilute 5 ml of this solution to 25ml with the solvent mixture, filter and use.

6.1.4 Chromatographic system:

- **Column:** C18, (150 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.5 ml/min
- **Wavelength:** 240 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Column temperature:** Ambient
- **Mobile Phase:** A mixture of 20 volumes of buffer solution prepared by dissolving 3.85 ammonium acetate in 1000ml of water, add 1ml of triethylamine, adjust pH to 5.5 with glacial acetic acid and 80 volumes of methanol

6.1.5 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 Montelukast in the syrup.

6.2 Levocetirizine Dihydrochloride: *Determine by liquid chromatography*

6.2.1 Test Solution: Pipette 10 ml of sample solution in 100ml volumetric flask add about 50 ml of mobile phase, sonicate it for 10 min. Cool and make up the volume with same solvent, stir for 10 min, filter and use.

6.2.2 Reference Solution: Weigh accurately about 50 mg of Levocetirizine Dihydrochloride WS in 100 ml of volumetric flask; dissolve it with 40ml of mobile phase and sonicate it for 10 minutes. Cool and make up the volume with same solvent, stir for 5 minutes. Dilute 5ml of this solution to 50ml with same solvent, filter and use.

6.2.3 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.0 ml/min

- **Wavelength:** 230 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Column temperature:** Ambient
- **Mobile Phase:** A mixture of 65 volumes of 0.05M potassium dihydrogen orthophosphate adjust pH 6.0 with 10% w/v of sodium hydroxide and 35 volumes of Acetonitrile

6.2.4 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 Levocetirizine Dihydrochloride in the syrup.

7. Other tests: As per pharmacopoeial requirements.