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 Hydrochloride Dispersible Tablets

Analytical Profile No.: Monte Levocet DT 078/079/AP 112

Montelukast and Levocetirizine Hydrochloride Dispersible Tablets contain not less than 90.0% and not more than 110.0% of the stated amount of Montelukast and Levocetirizine hydrochloride.

Usual Strength: Each uncoated dispersible tablet contains:

Montelukast Sodium IP eq. to Montelukast 4 mg

Levocetrizine Hydrochloride IP 2.5 mg

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. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of 1% w/v sodium lauryl sulphate in water

Speed and Time: 50 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 5ml of the filtrate in 10ml of volumetric flask with mobile phase A.

2.3 Reference Solution (a): Dissolve 27.0 mg of Levocetirizine HCl RS in 100ml of volumetric flask with methanol.

2.4 Reference Solution (b): Dissolve 44mg of Montelukast sodium RS in 100ml of volumetric flask with methanol.

2.5 Combined Reference Solution: From the above reference solution (a) and (b) take 1 ml each and make up to 100ml with the mobile phase A. Further dilute 5ml of above solution in 10ml of volumetric flask with mobile phase A.

2.6 Procedure: Use chromatographic condition as described in assay using injection volume 100µl.

Calculate the percent release of Montelukast & Levocetirizine HCl.

2.7 Limit: Not less than 70 percent (D) of the stated amount of Montelukast & Levocetirizine HCl.

3. Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following solution as the test solution.

3.1 Test Solution: Place a tablet in a 100ml volumetric flask, add 70ml of solvent mixture, sonicate to disperse whole tablet with intermittent shaking. Cool, make up the volume to 100 ml with same solvent and Centrifuge.

4. Assay: *Determine by liquid chromatography*

4.1 Solvent mixture: A mixture of 30 volumes of buffer solution prepared by dissolving 0.7791g of ammonium acetate in 1000 ml of water & adding 0.1ml of glacial acetic acid and 70 volumes of acetonitrile.

4.2 Test Solution: Weigh a quantity of powder (sample) containing 25mg of Montelukast Sodium in a 100ml of volumetric flask, add 70ml of solvent mixture, sonicate for 15 minutes. Cool, make up the volume to 100 ml with same solvent and Centrifuge. Further dilute 5ml of this solution with 25ml of solvent mixture.

4.3 Reference solution (a): Dissolve 25mg of Montelukast sodium RS in 100ml of volumetric flask with solvent mixture.

4.4 Reference solution (b): Dissolve 13.5mg of LevocetirizineHCl RS in 100ml of volumetric flask with solvent mixture.

4.5 Combined Reference solution: Finally dilute 5ml of reference solution (a) and (b) with 25 ml of solvent mixture.

4.6 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µ particle size

- **Flow rate:** 1.0 ml/min
- **Wavelength:** 240 nm
- **Column Oven Temperature:** 35 ºC
- **Injection volume:** 20 µl
- **Mobile Phase:**

Mobile Phase A: Mixtures of 60 volume of buffer solution prepared by dissolving 0.7791g of ammonium acetate in 1000ml of water and add 0.1ml of glacial acetic acid and 40 volumes of acetonitrile.

Mobile Phase B: Acetonitrile

A gradient programmed using the conditions given below:

Time(min)	Mobile Phase A	Mobile Phase B
0	100	0
7	100	0
8	55	45
24	55	45
25	10	90
29	10	90
29.1	100	0
35	100	0

4.7 Procedure: Inject the reference solution five times and sample solutions. 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%. Measure the peak responses. Calculate the content of Montelukast & Levocetirizine HCl in the tablets.

5. Other tests: As per pharmacopoeial requirements.