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

Levosalbutamol & Beclomethasone Dipropionate Powder for Inhalation

Analytical Profile No.: Levosal Beclo 079/080/AP 107

Levosalbutamol & Beclomethasone Dipropionate Powder for Inhalation contains not less than 90.0% and not more than 125.0% of the stated amount of Levosalbutamol & Beclomethasone Dipropionate.

Usual Strength: Each capsule contains:

Levosalbutamol sulphate equivalent to Levosalbutamol 100 mcg

Beclomethasone Dipropionate 100 mcg

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.

2. Assay: *Determine by liquid chromatography*

2.1 Diluent: Homogeneous mixture of water, acetonitrile and methanol in the ratio of 30:35:35 and adjust pH 3.5 ± 0.05 with orthophosphoric acid.

2.2 Test solution: Randomly select 10 capsules and transfer entire content of the 10 capsules in 200 ml volumetric flask using funnel (ensure all the content of the capsules are transferred). Rinse the capsule from inside with about 50 ml of the diluent and transfer to the same volumetric flask through the funnel. Add about 70 ml of the diluent into the flask through the funnel so that all the content in the funnel gets transferred into the volumetric flask. Sonicate for 10 minutes, cool to room temperature and make up the volume with diluent.

2.3 Reference solution A: Weigh accurately 30 mg of Levosalbutamol W S in 100ml of volumetric flask, add 70 ml of diluent and sonicate to dissolve. Cool to room temperature, make up the volume with diluent and mix.

2.4 Reference solution B: Weigh accurately 50 mg of Beclomethasone Dipropionate W S in 100ml of volumetric flask, add 70 ml of diluent and sonicate to dissolve. Cool to room temperature, make up the volume with diluent and mix.

2.5 Combined Reference solution: Take 4 ml of reference solution A and 2 ml of reference solution B in 200 ml of volumetric flask and make up the volume with diluent.

2.6 Chromatographic system:

Column: Inertsil Sprint C18 (4.6mmX 150-mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 237 nm

Injection volume: 40µl

Column Temperature: 30ºC

Mobile Phase: A mixture of 30 volume of Buffer, 35 volume of Acetonitrile and 35 volume of Methanol.

Buffer: Prepare a mixture of 1.38 gm of Sodium dihydrogen orthophosphate monohydrate and 2.44 gm of 1-Decane sulphonic acid sodium salt anhydrous in 1000 ml water, adjust pH 3.5± 0.05 with orthophosphoric acid.

2.7 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 Levosalbutamol & Beclomethasone Dipropionate in Levosalbutamol Sulphate & Beclomethasone Dipropionate Powder for Inhalation.

3. Other tests: As per pharmacopoeial requirements.