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

Analytical profile of Levosalbutamol Syrup

Analytical Profile No.: Levosal 078/079/AP 110

Levosalbutamol Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Levosalbutamol.

Usual Strength: Each 5 ml contains:

Levosalbutamol Sulphate equivalent to Levosalbutamol 1mg

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. Wt/ml: As per manufacturer's specification

3. pH: As per manufacturer's specification

4. Assay: *Determine by liquid chromatography*

4.1 Test Solution: Place 5 ml of syrup in 100ml of volumetric flask, add about 50 ml of mobile phase, sonicate, cool at room temperature and make up the volume to 100 ml with mobile phase.

4.2 Reference solution: Weigh accurately 100 mg of Levosalbutamol WS in 100ml of volumetric flask, add about 50 ml of mobile phase, sonicate, cool at room temperature and make up the volume to 100 ml with mobile phase. Further dilute 1ml of this solution to 100ml with mobile phase.

4.3 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 276 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Mobile Phase:** A mixture of 80 volumes of Buffer and 20 volumes of Acetonitrile

Buffer: 6.8 gm of potassium dihydrogen orthophosphate in 1000 ml water. Maintain pH 3.0 with orhophoshoric acid.

4.4 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 Levosalbutamol in syrup.

5. Other tests: As per pharmacopoeial requirements.