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

Analytical profile of Ambroxol Hydrochloride Syrup

Analytical Profile No.: Ambrx 076/077/ AP 073

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

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. pH: As per manufacturer's specification

3. wt/ml: As per manufacturer's specification

4. Assay:

4.1 Test Solution: Shake well and weigh sample equivalent to 30mg of Ambroxol Hydrochloride in 100ml volumetric flask, add about 70ml water, sonicate for 15 minutes and make up the volume with same solvent.

4.2 Reference Solution: Weigh accurately about 60 mg of Ambroxol Hydrochloride WS in a 100 ml volumetric flask, add about 70ml water, sonicate for 15 minutes and make up the volume with same solvent. Dilute 5ml of resulting solution to 10ml with same solvent.

4.3 Chromatographic system

- Column: C18 (15 cm X 4.6 mm), 5 µm
- Flow rate: 1ml/min
- Detector: UV
- Wavelength: 248 nm
- Injection volume: 10 µl
- Mobile Phase: a mixture of equal volumes of buffer solution prepared by dissolving 1.32g of ammonium phosphate dibasic in 900ml water, adjusted to pH 7.0 with Orthophosphoric acid and diluted to 1000ml with water and Acetonitrile

4.4 Procedure: Inject the reference solution five times and the test solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0%. Measure the peak response. Calculate the content of Ambroxol Hydrochloride in the syrup.

5. Other tests: As per pharmacopoeial requirement.