DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Ambroxol Hydrochloride Drops

Analytical profile no.: Ambrx D 077/078/AP 094

Ambroxol Hydrochloride Drops contains not less than 90% and not more than 110% 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.

Tests:

2. pH: As per manufacturer's specification

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

4. Assay: *Determine by liquid chromatography*

4.1 Test solution: Shake well and weigh accurately about sample in gm equivalent to 15 mg of Ambroxol Hydrochloride (i.e; 2 x weight per ml of the syrup) in 100ml volumetric flask. Make up the volume with water up to the mark and stir mechanically for 30 minutes. Mix well and filter through 0.2 µm filter paper.

4.2 Reference solution: Weigh accurately about 37.5 mg of Ambroxol Hydrochloride WS and transfer into 50 ml volumetric flask. Add about 30 ml of water, and sonicate, cool at room temperature and make up the volume to 50 ml with same solvent. Further dilute 10ml of this solution to 50ml with same solvent. Mix well and filter through 0.2 µm filter paper.

4.3 Chromatographic system:

- **Column:** C18, (150 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.5 ml/min
- **Wavelength:** 248 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Column temperature:** 30 °C
- **Mobile Phase:** A mixture of 50 volumes of buffer and 50 volumes of Acetonitrile

- **Buffer:** Dissolve 1.32 gm of Diammonium hydrogen phosphate in 1000ml of water. Adjust pH to 7.0 with dilute phosphoric acid

4.4 Procedure: Inject the reference solution five/six 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 Ambroxol Hydrochloride in the drops.

5. Other tests: As per pharmacopoeial requirement.