

DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Ambroxol Hydrochloride Syrup

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

Ambroxol Hydrochloride Syrup 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 should correspond to the peak in the chromatogram obtained with the reference solution.

Tests:

2. pH: 4.0 to 6.0

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

4. Assay: *Determine by liquid chromatography*

4.1 Test Solution:

Shake well and weigh sample equivalent to 30 mg of Ambroxol Hydrochloride in 100 ml volumetric flask, add about 70 ml water, sonicate for 15 minutes and make up the volume with same solvent. Filter the resulting solution through 0.2 µm membrane filter.

4.2 Reference Solution:

Weigh accurately about 60 mg of Ambroxol Hydrochloride RS in a 100 ml volumetric flask, add about 70 ml water, sonicate for 15 minutes and make up the volume with same solvent. Dilute 5 ml of resulting solution to 10 ml with same solvent. Filter the resulting solution through 0.2 µm membrane filter.

4.3 Chromatographic system:

Column: C18 (15 cm X 4.6 mm), 5 µm

Flow rate: 1 ml/min

Wavelength: 248 nm

Injection volume: 10 µl

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Column temperature: Ambient

Detector: UV

Mobile Phase: a mixture of equal volumes of buffer solution prepared by dissolving 1.32 g of ammonium phosphate dibasic in 900 ml water, adjusted to pH 7.0 with Orthophosphoric acid and diluted to 1000 ml with water and Acetonitrile

4.4 Procedure:

Inject the reference solution five times and 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 is not more than 2.0 %. Calculate the content of Ambroxol Hydrochloride in the syrup.

5. Other tests: As per pharmacopoeial requirement.