

Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section
Analytical profile of Bromhexine Hydrochloride & Terbutaline Sulphate
Syrup

Analytical Profile No.: BROM TERB 075/076/AP052

Bromhexine Hydrochloride & Terbutaline Sulphate Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Bromhexine Hydrochloride & Terbutaline Sulphate.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution.

2. pH: As per manufacturer's specification

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

4. Assay

4.1 Solvent Mixture: Buffer pH 3.0 (mobile phase A)

4.2 Test Solution: Weigh accurately 2.5gm of the syrup in 50 ml volumetric flask. Add about 30 ml of solvent mixture and sonicate for about 15 minutes. Cool the solution to room temperature and make up the volume to 50 ml with same solvent & mix

4.3 Reference Solution:

Terbutaline Sulphate Reference Stock Solution: Weigh accurately about 37.5 mg of Terbutaline Sulphate WS in 50 ml volumetric flask, add about 30 ml of solvent mixture and sonicate for about 15 minutes. Cool the solution to room temperature and make up the volume to 50 ml with same solvent & mix.

Bromhexine Hydrochloride Reference Stock Solution: Weigh accurately about 50 mg of Bromhexine Hydrochloride WS in 50 ml volumetric flask, add 2ml of methanol and sonicate to dissolve. Make up the volume to 50 ml with solvent mixture.

Composite Reference Solution: Dilute 1 ml of Terbutaline Sulphate reference stock solution and 2 ml of Bromhexine Hydrochloride reference stock solution to 50 ml with solvent mixture.

4.4 Chromatographic system:

Column : (150 × 4.6) mm; 5 micron, ODS (C18)

Flow rate : 1.0 ml/ min.

Injection volume : 10 µl

Wavelength : Dual at 280 nm (for Terbutaline) and 248 nm (for Bromhexine)

Column Oven Temperature: 35 °C

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Mobile Phase A: Phosphate buffer pH 3.0 prepared by dissolving 8.95gm of disodium hydrogen phosphate dodecahydrate and 3.40gm of potassium dihydrogen orthophosphate in 1000ml of water and adjusting the pH with orthophosphoric acid or 2N sodium hydroxide.

Mobile Phase B: Acetonitrile

Gradient Programming:

Time (minutes)	Mobile Phase A (%)	Mobile Phase B (%)
0	85	15
4	85	15
6	60	40
14	60	40
16	85	15
19	85	15

4.5 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. The 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 response. Calculate the content of Terbutaline Sulphate and Bromhexine Hydrochloride in syrup

5. Other tests: As per pharmacopoeial requirement.