Bromhexine Hydrochloride & Terbutaline Sulphate Syrup

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

Bromhexine Hydrochloride & Terbutaline Sulphate Syrup contains not less than 90 % and not more than 110 % each of the stated amounts of Bromhexine hydrochloride and Terbutaline sulphate.

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: 3.5 to 5

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

4. Assay: *Determine by Liquid Chromatography*

4.1 Test Solution: Weigh accurately 2.5 gm of the syrup in 50 ml volumetric flask. Add about 30 ml of diluent and sonicate for about 15 minutes. Cool the solution to room temperature and make up the volume to 50 ml with diluent. Filter through 0.2 micron filter paper.

4.2 Reference Solution:

4.2.1 Terbutaline Sulphate Reference stock solution: Weigh accurately about 37.5 mg of Terbutaline Sulphate reference standard in 50 ml volumetric flask, add about 30 ml of diluent and sonicate for about 15 minutes. Cool the solution to room temperature and make up the volume to 50 ml with diluent.

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

4.2.3 Mix Reference Solution: Dilute 1 ml of Terbutaline Sulphate standard stock solution and 2 ml of Bromhexine Hydrochloride Reference Stock Solution to 50 ml with diluent. Filter through 0.2 micron filter paper.

4.3 Chromatographic system:

Column: C18, 150 x 4.6 mm, 5µm
Flow rate: 1.0 ml/min
Wave length: 280 nm (for Terbutaline) and 248 nm (for Bromhexine)
Injection volume: 10 µl
Column Temperature: 35 ºC
Mobile phase A: Phosphate buffer pH 3.0
Mobile Phase B: Acetonitrile
Diluent: Mobile phase A

Use gradient programming as given below:

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

4.4 Procedure: Inject the reference solution five 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 in not more than 2.0%. Calculate the content of Terbutaline Sulphate and Bromhexine Hydrochloride in syrup.

5. Other tests: As per pharmacopoieal requirement.