

**ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON  
PHARMACOPOEIAL PRODUCT  
DEPARTMENT OF DRUG ADMINISTRATION  
National Medicines Laboratory**

**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 amount of bromhexine hydrochloride and 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:** 3.5 to 5

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

**4. Assay:** Determine by thin layer chromatography

**4.1 Chromatographic system:**

**Column:** C18, 150 X 4.6 mm, 5 $\mu$

**Flow rate:** 1.0 ml/min

**Wave length:** Dual at 280 nm (for Terbutaline) and 248 nm (for Bromhexine)

**Injection volume:** 10  $\mu$ l

**Column Temperature:** 35 °C

**Mobile phase**

**Mobile Phase A:** Phosphate buffer pH 3.0.

**Mobile Phase B:** Acetonitrile

**Gradient Programming:**

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

**Diluent:** Buffer pH 3.0 (mobile phase A)

**4.3 Test Solution:**

Weigh accurately 2.5gm 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.

**4.4 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 diluent and sonicate for about 15 minutes. Cool the solution to room temperature and make up the volume to 50 ml with diluent.

**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 diluent.

**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.

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**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 in not more than 2.0%.

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

**4.6 Other tests:** As per pharmacopoeial requirement.