

**Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section**

Analytical profile of Bromhexine HCl, Chlorpheniramine Maleate & Phenylephrine Hydrochloride Syrup

Analytical Profile No.: Brom Chlor Phen 077/078/AP 087

Bromhexine Hydrochloride, Chlorpheniramine Maleate & Phenylephrine Hydrochloride Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Bromhexine Hydrochloride, Chlorpheniramine Maleate & Phenylephrine Hydrochloride.

Usual Strength: Each 5ml contains

Bromhexine Hydrochloride 4mg

Chlorpheniramine Maleate 2mg

Phenylephrine HCl 5mg

1. Identification:

In the Assay, the principle peaks in the chromatogram obtained with the test solution corresponds to the peaks 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 the contents of the bottle and pipette out 5 ml of syrup into a 25 ml volumetric flask. Add about 15 ml of methanol & sonicate for about 10 mins to dissolve, cool to room temperature & make up the volume to 25 ml with the same solvent. Filter the resulting solution & dilute 5 ml of the filtrate to 25 ml with mobile phase.

4.2 Reference Solution:

4.2.1 Chlorpheniramine Maleate stock solution: Weigh accurately about 25 mg of Chlorpheniramine Maleate WS in 50 ml volumetric flask. Add about 30 ml of methanol, sonicate for about 10 minutes to dissolve & make up the volume with same solvent.

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4.2.2 Bromhexine Hydrochloride stock solution: Weigh accurately about 25 mg of Bromhexine Hydrochloride WS in 50 ml volumetric flask. Add about 30 ml of methanol, sonicate for about 10 minutes to dissolve & make up the volume with same solvent.

4.2.3 Phenylephrine Hydrochloride stock solution: Weigh accurately about 25 mg of Phenylephrine Hydrochloride WS in 50 ml volumetric flask. Add about 30 ml of methanol, sonicate for about 10 minutes to dissolve & make up the volume with same solvent.

4.2.4 Combined reference solution: Take 2 ml Chlorpheniramine Maleate stock solution, 5 ml Bromhexine Hydrochloride stock solution & 5 ml Phenylephrine Hydrochloride stock solution in 50 ml volumetric flask & make up the volume with mobile phase.

4.3 Chromatographic system:

- **Column:** Nitrile, 15 cm x 4.6 mm, 5 μ m particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 278 nm
- **Injection volume:** 20 μ l
- **Detector:** UV/PDA
- **Column temperature:** ambient
- **Mobile Phase:** A mixture of 40 volumes of buffer, 50 volumes of methanol & 10 volumes of Acetonitrile
- **Buffer:** Dissolve 6.8 g of potassium dihydrogen phosphate in 1000 ml of water. Adjust the pH to 5.8 with 20% sodium hydroxide solution

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, tailing factor is not more than 2.0, the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Chlorpheniramine Maleate, Bromhexine Hydrochloride & Phenylephrine Hydrochloride in the syrup.

5. Other tests: As per pharmacopoeial requirement.