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

Analytical profile of Dextromethorphan Hydrobromide, Chlorpheniramine Maleate & Phenylephrine Hydrochloride Syrup

Analytical Profile No.: Dex Chlor Phen 077/078/AP 085

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

Usual Strength: Each 5ml contains

Dextromethorphan Hydrobromide 15mg

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 take 5 ml of syrup into a 100 ml volumetric flask. Dissolve it with 70 ml of diluent by sonicating for 15 minutes & make up the volume with same solvent.

4.2 Reference Solution:

4.2.1 Dextromethorphan Hydrobromide (Stock Solution A): Weigh accurately & transfer about 30 mg of Dextromethorphan Hydrobromide WS in 100 ml volumetric flask. Dissolve it with 70 ml of diluent by sonicating for 15 minutes & make up the volume with same solvent.

4.2.2 Chlorpheniramine Maleate & Phenylephrine Hydrochloride (Stock Solution B): Weigh accurately and transfer about 50 mg of Phenylephrine Hydrochloride WS & 20 mg of Chlorpheniramine Maleate in 100 ml volumetric flask. Dissolve it with 70 ml of diluent by sonicating for 15 minutes & make up the volume with same solvent.

4.2.4 Combined reference solution: Dilute 10 ml of stock solution A & 2 ml of stock solution B in 20 ml volumetric flask and make up the volume with diluent.

4.3 Chromatographic system:

- **Column:** C18, 25 cm x 4.6 mm, 5µm particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 220 nm
- **Injection volume:** 20 µl
- **Detector:** UV/PDA
- **Column temperature:** 25 °C
- **Mobile Phase A:** Dissolve 1.0 ml of triethylamine & 1.08 g of 1-Octane sulfonic acid sodium salt in 1000ml HPLC grade water. Adjust the pH to 3.2 using dilute ortho phosphoric acid.
- **Mobile Phase B:** Acetonitrile
- **Diluent:** Acetonitrile:Mobile Phase A (50:50)

Use time programming as given below:

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0	70	30
2	70	30
8	60	40
12	45	55
20	40	60
22	70	30
30	70	30

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 Dextromethorphan Hydrobromide, Chlorpheniramine Maleate & Phenylephrine Hydrochloride in the syrup.

5. Other tests: As per pharmacopoeial requirement.