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

Dextromethorphan Hydrobromide and Chlorpheniramine Maleate Syrup

Analytical Profile No.: Dex Chlor 079/080/AP 120

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

Usual Strength: Each 5 ml contains:
Dextromethorphan Hydrobromide 10 mg
Chlorpheniramine Maleate 2 mg

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. pH: As per manufacturer's specification

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

4. Microbial Limit Test: As per IP latest edition

5. Absence of specified Microorganism: As per IP latest edition

6. Assay: *Determine by liquid chromatography*

6.1 Diluent: Water: Acetonitrile: 80:20

6.2 Test solution: Weigh accurately and transfer the sample equivalent to about 10 mg of Dextromethorphan Hydrobromide into a 50 ml clean and dry volumetric flask. Add about 30 ml of diluent, sonicate, cool to room temperature and make up the volume to 50 ml with same solvent.

6.3 Reference solution: Weigh accurately 100mg of Dextromethorphan Hydrobromide WS and 20 mg of Chlorpheniramine Maleate WS and transfer into 100 ml clean and dry volumetric flask. Add about 60 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume to 100 ml with same solvent. Further dilute 10 ml of this solution to 50 ml with diluent and mix well.

6.4 Chromatographic system:

- **Column:** Kinetex XB, C18, (250 x 4.6) mm, 5 µ particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 272 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Column temperature:** Ambient
- **Mobile Phase A:** Buffer Solution
- **Mobile Phase B:** Acetonitrile
    - **Buffer:** Add 3 ml of Triethylamine in 1000 ml of water and add 1.5 gm of 1 – octane sulphonic acid sodium salt anhydrous and mix well. Adjust the pH to 2.4± 0.05 with dilute Orthophosphoric acid.

Gradient program

Time (in minutes)	% Mobile phase -A	% Mobile phase-B
0.01	80	20
5.00	80	20
15.00	65	35
20.00	65	35
25.00	80	20
30.00	80	20
30.01	Stop	-

6.5 Procedure: Inject the reference solution five times. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0%. Inject the test solution. Measure the peak responses. Calculate the content of Dextromethorphan Hydrobromide and Chlorpheniramine Maleate in syrup.

7. Other tests: As per pharmacopoeial requirements.