

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

Analytical profile of Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate Syrup

Analytical Profile No.: Para Chlor Phen 079/080/AP 119

Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate Syrup.

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: Methanol: 45:55

6.2 Test solution: Place 10 ml of syrup in 100 ml of volumetric flask. Add about 70 ml of diluent, sonicate, cool to room temperature and make up the volume to 100 ml with same solvent. Dilute 2 ml of the solution to 25 ml with mobile phase.

6.3 Reference solution:

Standard (A):

Weigh accurately 25 mg of Chlorpheniramine Maleate WS and transfer into 25ml of volumetric flask. Add about 15 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume to 25 ml with same solvent.

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Standard (B):

Weigh accurately 25 mg of Phenylephrine WS and transfer into 50ml of volumetric flask. Add about 30 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume to 50 ml with same solvent.

Composite Standard: Weigh about 125 mg of paracetamol WS and transfer into 50 ml volumetric flask, add about 25 ml of diluent and sonicate to dissolve. Add 1 ml of Standard A and 5 ml of standard B and make up the volume with diluent.

6.4 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 μ particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 280 nm
- **Injection volume:** 10 μ l
- **Detector:** UV
- **Column temperature:** 30 °C
- **Mobile Phase:** A mixture of 90 volumes of buffer and 10 volumes of Acetonitrile
 - **Buffer:** Mix 135 ml of water and 165 ml of methanol. Adjust pH to 3.0 with dilute phosphoric acid. Then add 0.33 gm. of 1-octane sulphonic acid.

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 Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate in syrup.

7. Other tests: As per pharmacopoeial requirements.