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

Analytical profile of Tropicamide and Phenylephrine HCl Ophthalmic Solution

Analytical Profile No.: Trop Phen 075/076/AP038

Tropicamide and Phenylephrine HCl Ophthalmic Solution contains not less than 90.0% and not more than 110.0% of the stated amount of Tropicamide and Phenylephrine HCl.

1. Identification:

1.1 Tropicamide

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.

1.2 Phenylephrine HCl

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. Particulate matter (By Light Obscuration Particle Counter): As per Indian Pharmacopoeia (latest edition)

4. Sterility test: As per Indian Pharmacopoeia (latest edition)

5. Assay

5.1 Test Solution: Transfer an accurately measured volume of ophthalmic solution, equivalent to about 16 mg of tropicamide, (i.e; 2 ml) to a 100 ml volumetric flask, add 2 ml of dilute sulphuric acid (1 in 6), sonicate, cool to room temperature and make up the volume with mobile phase. Dilute 5 ml of this solution to 50ml volumetric flask with mobile phase.

5.2 Reference Solution:

Reference Solution A: Weigh accurately about 40 mg of Tropicamide RS and transfer into 50 ml volumetric flask. Dissolve it with 2 ml of dilute sulphuric acid (1 in 6), sonicate and make up the volume with mobile phase.

Reference Solution B: Weigh accurately about 50 mg of Phenylephrine HCl RS and transfer into 50 ml volumetric flask. Dissolve it with 10ml of mobile phase, add 10 ml of Reference solution A and make up the volume with mobile phase. Dilute 5 ml of this solution to 50ml volumetric flask with mobile phase.

5.3 Chromatographic system:

Column: (250 × 4.6) mm; 5 µm packing ODS (C18)

Flow rate: 1.2 ml/ min.

Wavelength: 257 nm

Injection volume: 10 µl

Column Oven Temperature: 40 ºC

Mobile Phase: Dissolve 1.1 g of sodium 1-octane sulphonate in 1000ml of solution A, sonicate and filter.

Solution A: A mixture of methanol and water (58:42), pH adjusted to 3.0 with 3M orthophosphoric acid.

5.4 Procedure: Inject the reference solution five/six times and sample solutions. The test is not valid unless the resolution between Phenylephrine and Tropicamide is not less than 2, 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 in not more than 2.0%. Calculate the content of Phenylephrine and Tropicamide in the eye drop.

6. Other tests: As per pharmacopoeial requirements.