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

Analytical profile of Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl Tablets

Analytical Profile No.: Dex Tri Phen 075/076/AP049

Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl.

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. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml of water

Speed and Time: 75 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution

Dextromethorphan HBr: Weigh accurately about 30mg of Dextromethorphan HBr WS in 50ml volumetric flask and dissolve and make up the volume with water.

Triprolidine HCl: Weigh accurately about 25mg of Triprolidine HCl WS in 50ml volumetric flask and dissolve and make up the volume with water.

Phenylephrine HCl: Weigh accurately about 50mg of Phenylephrine HCl WS in 50ml volumetric flask and dissolve and make up the volume with water.

Combined Reference Solution: Take 10ml of Dextromethorphan HBr WS solution, 2ml of Triprolidine HCl WS solution and 2ml of Phenylephrine HCl WS solution in 50ml volumetric flask and make up the volume with water.

2.4 Procedure: Use the chromatographic system as described in the Assay using 20 µl as injection volume. Inject the reference solution and the test solution. Calculate the percent release of Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl.

2.5 Limit: NLT 75 per cent (D) of the stated amount

3. Uniformity of content

Determine by liquid chromatography, as described in the Assay, using the following test solution.
Test solution: Transfer one tablet in 50ml of volumetric flask, disperse the tablet in few drops of water and add about 30ml mobile phase, sonicate to dissolve and make up the volume with same solvent. Dilute 10ml of this solution to 50ml with the mobile phase.

4. Assay

4.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 30 mg of Dextromethorphan HBr in 50 ml volumetric flask, add 30 ml of mobile phase, sonicate to dissolve and make volume to 50 ml with same solvent. Dilute 10 ml of this solution to 50 ml with same solvent and mix.

4.2 Reference Solution

Dextromethorphan HBr: Weigh accurately about 30mg of Dextromethorphan HBr WS in 50ml volumetric flask and dissolve and make up the volume with mobile phase.

Triprolidine HCl: Weigh accurately about 25mg of Triprolidine HCl WS in 50ml volumetric flask and dissolve and make up the volume with mobile phase.

Phenylephrine HCl: Weigh accurately about 50mg of Phenylephrine HCl WS in 50ml volumetric flask and dissolve and make up the volume with mobile phase.

Combined Reference Solution: Take 10ml of Dextromethorphan HBr WS solution, 2ml of Triprolidine HCl WS solution and 2ml of Phenylephrine HCl WS solution in 50ml volumetric flask and make up the volume with mobile phase.

4.3 Chromatographic System

Column: C18, (25cm x 4.6mm, 5µ)

Flow rate: 1.8ml/min

Wavelength: 220nm

Injection volume: 20µl

Mobile Phase: A mixture of 70 volume of bBuffer & 30 volume of ACN

Buffer solution: Dissolve 1g of octanesulphonic acid and 1 ml of Triethylamine in 1000ml of water. Then adjust to pH 3.2 with orthophosphoric acid.

4.4 Procedure: Inject the reference solution five/six 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 in not more than 2.0% and unless the resolution between Triprolidine HCl and Dextromethorphan HBr is not less than 2. Measure the peak responses. Calculate the content of Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl.

5. Other tests: As per pharmacopoeial requirements.