Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl Tablets

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

Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl Tablets contain not less than 90 % and not more than 110 % of the stated amount of Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl.

1. Identification:

1.1 Dextromethorphan HBr: In the assay, the principle peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution of Dextromethorphan HBr.

1.2 Triprolidine HCl: In the assay, the principle peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution of Triprolidine HCl.

1.3 Phenylephrine HCl: In the assay, the principle peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution of Phenylephrine HCl.

Tests:

2. Dissolution:

2.1 Dissolution Parameter

Apparatus:	Paddle
Medium:	900 ml, water
Speed and Time:	75 rpm for 45 minutes
Temperature:	37 ± 0.5°C

Withdraw a suitable volume of the medium and filter.

Determine by Liquid Chromatography

2.2 Test Solution: Filter the resulting solution through 0.2 µm membrane filter. Use the filtrate.

2.3 Reference Solution:

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

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

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

2.3.4 Mix Standard Solution: Take 10 ml of Dextromethorphan HBr reference solution, 2 ml of Triprolidine HCl reference solution and 2 ml of Phenylephrine HCl reference solution in 50 ml volumetric flask and make up the volume with water. Filter the resulting solution through 0.2 µm membrane filter.

2.4 Chromatographic System and Procedure: Proceed as directed under Assay and calculate the % release of Dextromethorphan HBr, Triprolidine HCl and Phenylephrine HCl.

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

3. Uniformity of content:

3.1 Test solution: Transfer one tablet in 50 ml of volumetric flask, disperse the tablet in few drops of water and add about 30 ml mobile phase, sonicate to dissolve and make up the volume with same solvent. Dilute 10 ml of this solution to 50 ml with the mobile phase. Filter the final solution through 0.2 µm membrane filter.

3.2 Reference solution: same as assay

3.3 Chromatographic System and Procedure: same as assay

3.4 Limit: 85 – 115 % of the stated amount

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 filter the final solution through 0.2 µm membrane filter.

4.2 Reference Solution:

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

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

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

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

4.3 Chromatographic System

Column:	25 cm x 4.6 mm, C18
Injection volume:	20 µl
Flow rate:	1.8 ml/min
Wavelength:	220 nm
Detector:	UV
Column temperature:	Ambient

Mobile Phase: Buffer: ACN (70:30)

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

4.4 Procedure: Inject the reference solution five times and test 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, 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 and Phenylephrine HCl per tablet.

5. Other tests: As per pharmacopoieal requirement.