DEPARTMENT OF DRUG ADMINISTRATION

National Medicines Laboratory

ANALYTICAL METHOD VALIDATION COMMITTEE

Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl Syrup

Analytical profile no.: Dex Tri Phen S 078/079/AP 099

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

Usual Strength: Each 5 ml contains:

Dextromethorphan HBr 10 mg,

Triprolidine HCl 1.25 mg

Phenylephrine HCl 5 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. Assay: *Determine by liquid chromatography*

4.1 Solvent Mixture: Mix methanol and water in the ratio (58:42) and adjust pH 3.0 with phosphoric acid.

4.2 Test solution: Shake well and weigh accurately 5 ml of sample (about 5.686 gm) in 100ml volumetric flask. Add about 70 ml of solvent mixture, sonicate, cool to room temperature and make up the volume to 100 ml with same solvent.

4.3 Reference solution:

Reference Solution A: Weigh accurately 12.5 mg of Triprolidine HCl WS and 50 mg Phenylephrine HCl WS in 100 ml volumetric flask, add 70 ml solvent mixture, sonicate to dissolve and dilute to the mark with solvent mixture.

Reference Solution B: Weigh accurately 50 mg of Dextromethorphan HBr WS in 100 ml volumetric flask, add 70 ml solvent mixture, sonicate to dissolve and dilute to the mark with solvent mixture.

Final Reference Solution: Add 5 ml of reference solution A & 10 ml reference solution B in 50 ml volumetric flask and make up the volume to 50 ml with solvent mixture.

4.4 Chromatographic system:

- **Column:** C18, (150 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.3 ml/min
- **Wavelength:** 280 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Column temperature:** Ambient
- **Mobile Phase:** Dissolve 1.1 gm of sodium octanesulphonic acid in 1000 ml solvent mixture.

4.5 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 HBr, Triprolidine HCl & Phenylephrine HCl in syrup.

5. Other tests: As per pharmacopoeial requirement.