ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT
DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory

Fexofenadine Hydrochloride Suspension

Analytical Profile No.: Fex 073/074/AP 009

Fexofenadine Hydrochloride suspension contains not less than 90% and not more than 110% of the stated amount of Fexofenadine Hydrochloride.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Fexofenadine Hydrochloride.

2. pH: 5 to 7

3. wt/ml: As per the manufacturer's specification

4. Assay: Determine by liquid chromatography

4.1 Solvent Mixture: Prepare a mixture of Acetonitrile and Acid solution (75:25)

4.2 Test Solution:

Weigh accurately the sample equivalent to 30 mg of fexofenadine HCl and transfer into 100 ml volumetric flask. Add about 50 ml of solvent mixture and sonicate for about 10 minutes. Cool the solution to room temperature and make up the volume to 100 ml with solvent mixture. Centrifuge the sample solution. Dilute 2 ml of the resulting solution to 50 ml with mobile phase. Filter through 0.2 micron filter paper.

4.3 Reference Solution:

Weigh accurately about 30 mg of working standard of Fexofenadine HCl and transfer into 100 ml volumetric flask, add about 50 ml of solvent mixture and sonicate for about 10 minutes. Cool the solution to room temperature and make up the volume to 100 ml with solvent mixture. Dilute 2 ml of the resulting solution to 50 ml with mobile phase. Filter through 0.2 micron filter paper.

4.4 Chromatographic system:

Column: C18 150 X 4.6 mm Octadecylsilane (ODS) 5µ

Flow rate: 1.5 ml/min

Wave length: 220 nm

Injection volume: 20 µl

Column Temperature: 35 ^{o}C

Detector: UV

Mobile phase

Acid solution: Dilute 1.7 ml of glacial acetic acid with water to 1 litre.

Buffer solution: Dilute 15 ml of a solution containing a mixture of acetonitrile and triethylamine (1:1) with acid solution to 1 litre. Adjust the pH to 5.5 with phosphoric acid.

Mobile phase: Prepare a filtered and degassed mixture of Buffer solution and acetonitrile in the ratio (64:36).

4.5 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. The 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 fexofenadine HCl in the suspension.

5. Other tests: As per pharmacopoeial requirement