DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

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 test solution should correspond to the peak in the chromatogram obtained with the reference solution of Fexofenadine Hydrochloride.

Tests:

2. pH: 5 to 7

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

4. Assay: *Determine by liquid chromatography*

Solution A: Dilute 1.7 ml of glacial acetic acid with water to 1 litre.

Diluent: Prepare a mixture of Acetonitrile and Solution A (75:25)

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

4.1 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 diluent and sonicate for about 10 minutes. Cool the solution to room temperature and make up the volume to 100 ml with diluent. Centrifuge the sample solution. Dilute 2 ml clear supernatant solution to 50 ml with mobile phase. Filter through 0.2 µm membrane filter paper.

4.2 Reference Solution: Weigh accurately about 30 mg Fexofenadine HCl reference standard and transfer into 100 ml volumetric flask, add about 50 ml of diluent and sonicate for about 10 minutes. Cool the solution to room temperature and make up the volume to 100 ml with diluent.

Dilute 2 ml of the resulting solution to 50 ml with mobile phase. Filter through 0.2 µm membrane filter paper

4.3 Chromatographic System:

Column: a stainless steel column 15 cm x 4.6 mm, packed with octadecyl silane bonded to porous silica (5 µm),

Injection volume: 20 µl,

Flow rate: 1.5 ml per minute,

Detector: spectrophotometer set at 220 nm,

Column temperature: 35 ℃

Mobile phase: a mixture of 64 volumes of buffer solution and 36 volumes of acetonitrile

4.4 Procedure: Inject 20 µl of reference solution five times using the above mentioned chromatographic conditions. 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 in not more than 2.0 %. Inject test solution, blank solution and calculate the content of fexofenadine HCl in the suspension.

5 Other tests: As per pharmacopoeial requirements.