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

Analytical profile of Fexofenadine HCl suspension

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

Fexofenadine HCl suspension contains not less than 90.0% and not more than 110.0% of the stated amount of Fexofenadine HCl.

Usual strength: 30 mg/ 5 ml

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.

Tests:

2. pH: As per manufacturer's specification

3. Wt/ml: As per manufacturer's specification

4. Assay: *Deteremine by liquid chromatography*

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

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

4.2 Test Preparation: 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 of the resulting solution to 50 ml with mobile phase.

4.3 Standard Preparation: Weigh accurately about 30 mg of Fexofenadine HCl RS 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.

4.4 Chromatographic system:

Column: (150 × 4.6) mm; 5 micron, ODS (C18)

Flow rate: 1.5 ml/ min.

Injection volume: 20 µl

Wavelength: 220 nm

Temperature: 35 ºC

Mobile phase: 64 volume of Buffer solution and 36 volume of Acetonitrile

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.

4.5 Procedure: Inject the reference solution five/six times and test 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.