Edition: BP 2025 (Ph. Eur. 11.6 update)

Fexofenadine Tablets

General Notices

Action and use

Histamine H_1 receptor antagonist; antihistamine.

DEFINITION

Fexofenadine Tablets contain Fexofenadine Hydrochloride. They may be coated.

The tablets comply with the requirements stated under Tablets and with the following requirements.

PRODUCTION

The manufacturing process of Fexofenadine Hydrochloride, used in the formulation of Fexofenadine Tablets, is validated to ensure that the content of the enantiomer impurity B is not more than 0.1%.

Content of fexofenadine hydrochloride, $C_{32}H_{39}NO_4$,HCl

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 30 mg of Fexofenadine Hydrochloride with 10 mL of *methanol* for 5 minutes, filter and evaporate the filtrate to dryness. The *infrared absorption spectrum* of the dried residue, Appendix II A, is concordant with the *reference spectrum* of fexofenadine hydrochloride (*RS 459*).

TESTS

Dissolution

Comply with the *dissolution test for tablets and capsules*, Appendix XII B1.

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of 0.001M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) After 45 minutes withdraw a sample of the medium and filter. Use the filtered medium, diluted with 0.001M *hydrochloric acid* if necessary, to produce a solution expected to contain 0.003% w/v of Fexofenadine Hydrochloride.
(2) 0.003% w/v of *fexofenadine hydrochloride BPCRS* in 0.001M *hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the total content of fexofenadine hydrochloride, $C_{32}H_{39}NO_4$,HCl, in the medium from the chromatograms obtained and using the declared content of $C_{32}H_{39}NO_4$,HCl in *fexofenadine hydrochloride BPCRS*.

LIMITS

The amount of fexofenadine hydrochloride released is not less than 75% (Q) of the stated amount.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in solvent A.

SOLVENT A

Equal volumes of *acetonitrile* and a buffer solution containing 0.05M *sodium dihydrogen orthophosphate monohydrate* and 0.006M *sodium perchlorate*. The pH of the buffer solution is adjusted to 2.0 with *orthophosphoric acid* before the addition of acetonitrile.

(1) Shake a quantity of powdered tablets containing 25 mg of Fexofenadine Hydrochloride with 25 mL of solvent A and filter.
(2) Dilute 1 volume of solution (1) to 100 volumes with solvent A and further dilute 1 volume of the resulting solution to 5 volumes with solvent A.
(3) 0.1% w/v of *fexofenadine impurity standard BPCRS* in solvent A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *phenylsilyl silica gel for chromatography* (5 µm) (Zorbax SB Phenyl is suitable).
(b) Use isocratic elution using the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 220 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

350 volumes of *acetonitrile* and 650 volumes of a buffer solution containing 0.05M *sodium dihydrogen orthophosphate monohydrate* and 0.006M *sodium perchlorate* the pH of which is adjusted to 2.0 with *orthophosphoric acid*. To the resulting solution add 3 volumes of *triethylamine* and mix.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the principal peaks due to Fexofenadine and impurity A is at least 10.

LIMITS

In the chromatogram obtained with solution (1):

multiply the peak area of any peak corresponding to impurity A by 1.4;
the area of any *secondary peak* corresponding to impurity A is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (0.6%);
the area of any *secondary peak* corresponding to impurity C is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%);
the area of any other *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas of all *secondary peaks* is not greater than 5 times the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).
Disregard any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of powdered tablets containing 50 mg of Fexofenadine Hydrochloride with 50 mL of solvent A and filter.
(2) 0.1% w/v of *fexofenadine hydrochloride BPCRS* in solvent A.
(3) 0.1% w/v of *fexofenadine impurity standard BPCRS* in solvent A.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the principal peaks due to Fexofenadine and impurity A is at least 10.

DETERMINATION OF CONTENT

Calculate the content of $C_{32}H_{39}NO_4$,HCl in the tablets using the declared content of $C_{32}H_{39}NO_4$,HCl in *fexofenadine hydrochloride BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A and C listed under Fexofenadine Hydrochloride.