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Loratadine Tablets

Details for the public consultation of this monograph are as follows:

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Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. **Dissolution** new test added **Impurity H** test deleted **Related substances** Disregard limit and system suitability revised

Action and use

Histamine H_1 receptor antagonist; antihistamine.

DEFINITION

Loratadine Tablets contain Loratadine.

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

Content of loratadine, $C_{22}H_{23}ClN_2O_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Extract a quantity of the powdered tablets containing 50 mg of Loratadine with 20 mL of *acetone*, 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 loratadine *(RS 435)*.

TESTS

Dissolution

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

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.

(b) Use 900 mL of 0.1M hydrochloric acid, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 45 minutes withdraw a sample of the medium and measure the *absorbance* of the filtered sample, suitably diluted with the dissolution medium, if necessary, to produce a solution expected to contain 0.001% w/v of Loratadine, at the maximum at 277 nm, Appendix II B, using dissolution medium in the reference cell.

(2) Measure the *absorbance* of a 0.001% w/v solution of *loratadine BPCRS* in the dissolution medium using dissolution medium in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of loratadine, $C_{22}H_{23}ClN_2O_2$, in the medium from the absorbances obtained and using the declared content of $C_{22}H_{23}ClN_2O_2$ in *loratadine BPCRS*.

LIMITS

The amount of loratadine 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.

(1) Shake a quantity of powdered tablets containing 20 mg of Loratadine with 10 mL of *methanol* and filter. Dilute 1 volume of the filtrate to 2 volumes with the mobile phase.

(2) Dilute 1 volume of solution (1) to 100 volumes and further dilute 1 volume to 5 volumes with the mobile phase.

(3) 0.1% w/v of *loratadine impurity standard BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Inertsil ODS-3V is suitable).

(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 1.5 mL per minute.

(d) Use a column temperature of 40°.

(e) Use a detection wavelength of 220 nm.

(f) Inject 20 µL of each solution.

(g) Allow the chromatography to proceed for 5 times the retention time of loratadine.

MOBILE PHASE

30 volumes of *methanol*, 35 volumes of 0.05M *potassium dihydrogen orthophosphate*, previously adjusted to pH 2.8 with *orthophosphoric acid*, and 40 volumes of *acetonitrile*.

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to loratadine (retention time about 12 minutes) are: impurity F, about 0.9; impurity E, about 1.1 and impurity A, about 2.4.

SYSTEM SUITABILITY

The test is not valid unless:

in the chromatogram obtained with solution (3), the *resolution* between the peaks due to loratadine and impurity E is at least 1.5;

in the chromatogram obtained with solution (2), the *signal-to-noise ratio* of the principal peak is at least 40.

LIMITS

Identify any peaks corresponding to impurity A, impurity E and impurity F using solution (3) and the chromatogram supplied with *loratadine impurity standard BPCRS* and multiply the areas of these peaks by correction factors of 1.7, 1.9 and 1.6 respectively.

In the chromatogram obtained with solution (1):

the area of any *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 the *secondary peaks* is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%).

Disregard any peak with an area less than half 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 the powdered tablets containing 20 mg of Loratadine with 20 mL of *methanol* and filter. Dilute 1 volume of the filtrate to 10 volumes with the mobile phase.

(2) 0.01% w/v of *loratadine BPCRS* in the mobile phase.

(3) 0.1% w/v of *loratadine impurity standard BPCRS* in the mobile phase.

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* between the peaks due to loratadine and impurity E is at least 1.5.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{23}ClN_2O_2$ in the tablets using the declared content of $C_{22}H_{23}ClN_2O_2$ in *loratadine BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A to G listed under Loratadine.