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Loratadine Tablets

DEFINITION
Loratadine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of loratadine ($C_{22}H_{23}ClN_2O_2$).

IDENTIFICATION
- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
- **Procedure**

Buffer A: 0.01 M dibasic potassium phosphate (1.74 g/L of anhydrous dibasic potassium phosphate in water)

Buffer B: 0.6 M dibasic potassium phosphate (105 g/L of anhydrous dibasic potassium phosphate in water)

0.05 N hydrochloric acid: Transfer 500 mL of water into a 1000-mL volumetric flask, add 83 mL of hydrochloric acid, and dilute with water to volume. Transfer 50 mL of this solution into a 1000-mL volumetric flask and dilute with water to volume.

Mobile phase: Acetonitrile, methanol, and *Buffer A* (60:60:70). Adjust with 10% phosphoric acid to a pH of 7.2.

Diluent: Transfer 400 mL of *0.05 N hydrochloric acid* and 80 mL of *Buffer B* into a 1-L volumetric flask. Dilute with a mixture of acetonitrile and methanol (1:1) to volume.

Standard solution: 0.4 mg/mL of USP Loratadine RS in *Diluent*

Sample solution: Transfer 10 Tablets to a 250-mL volumetric flask, add 100 mL of *0.05 N hydrochloric acid*, and shake for 40 min or until the Tablets are completely disintegrated. Add 75 mL of a mixture of acetonitrile and methanol (1:1), and 20 mL of *Buffer B*, and mix for 5 min. Dilute with a mixture of acetonitrile and methanol (1:1) to volume.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing L7

Column temperature: 25°–35°

Flow rate: 1 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor: NLT 3.5

Tailing factor: NMT 1.7

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of loratadine ($C_{22}H_{23}ClN_2O_2$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Loratadine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of loratadine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 60 min

Standard solution: USP Loratadine RS at a known concentration in *Medium*

Sample solution: A filtered portion of the solution under test, suitably diluted with *Medium*, if necessary

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum absorbance at about 280 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of loratadine ($C_{22}H_{23}ClN_2O_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Loratadine RS in the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*, if needed

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of loratadine ($C_{22}H_{23}ClN_2O_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Buffer A, Buffer B, 0.05 N hydrochloric acid, Mobile phase, Diluent, and **Sample solution:** Proceed as directed in the *Assay*.

Standard solution: 0.8 µg/mL of USP Loratadine RS in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-µm packing L7

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 4.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of loratadine from the *Standard solution*

C_S = concentration of USP Loratadine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of loratadine in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Fluoroloratadine[a,b]	0.79	—
Loratadine	1.0	—
Any other individual impurity	—	0.1
Total impurities	—	0.1

[a] This is a process impurity and is included in the table for identification only. This impurity is controlled in the drug substance. It is not to be reported for the drug product and should not be included in the total impurities.

[b] Ethyl 4-(8-chloro-11-fluoro-5,6-dihydro-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridin-11-yl) piperidin-1-carboxylate.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store between 2° and 30°. Protect from excessive moisture if packaged in blisters.
- **USP Reference Standards** ⟨11⟩
  USP Loratadine RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
LORATADINE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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