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Loratadine Chewable Tablets

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

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Diluent: Chloroform and methanol (1:1)

Standard solution: 5 mg/mL of USP Loratadine RS in *Diluent*

Sample solution: Transfer a quantity of ground Chewable Tablets, equivalent to 25 mg of loratadine, to a centrifuge tube. Add 5 mL of *Diluent*, mix for 30 min, then centrifuge for 5 min. Use the clear supernatant.

Application volume: 5 µL

Developing solvent system: Ethyl ether and diethylamine (40:1)

Acceptance criteria: Meet the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Protect solutions containing loratadine from light.

Buffer A (phosphate buffer pH 7.2)**:** Dissolve 4.35 g of dibasic potassium phosphate in 950 mL of water. Add 1 mL of triethylamine, adjust with 10% phosphoric acid or 10% potassium hydroxide to a pH of 7.2, and dilute with water to 1 L.

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

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

Mobile phase: Acetonitrile, methanol and *Buffer A* (40:10:50)

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

Sample solution: Nominally 0.4 mg/mL of loratadine in *Diluent*. Prepare by transferring 20 Chewable Tablets to a suitable volumetric flask. Add *Diluent* to 40% of the volume of the flask, and shake for 40 min. Dilute with *Diluent* to volume, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

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 Chewable 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; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with 10% phosphoric acid to a pH of 2.80 ± 0.05.

Mobile phase: Acetonitrile, methanol, and *Buffer* (40:30:35)

Standard solution: 10 µg/mL of USP Loratadine RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

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 ($C_{22}H_{23}ClN_2O_2$) dissolved:

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

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)

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

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**

Protect solutions containing loratadine from light.

Mobile phase, Diluent, and **Sample solution:** Prepare as directed in the *Assay*.

System suitability solution: 0.8 µg/mL each of USP Loratadine Related Compound A RS, USP Loratadine Related Compound B RS, and USP Loratadine Related Compound C RS in *Diluent*

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 × 25-cm; 5-µm packing L7

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Relative standard deviation: NMT 10%, *Standard solution*

Resolution: NLT 5.5 between loratadine related compound A and loratadine related compound C; NLT 2.0 between loratadine related compound C and loratadine related compound B, *System suitability solution*

Tailing factor: NMT 2.0 for loratadine related compound A, *System suitability solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Reporting level for impurities: 0.05%

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Loratadine related compound A	0.20	1.0	0.05
Loratadine related compound C	0.32	0.63	0.10
Loratadine related compound B[a]	0.39	1.0	—
Loratadine	1.0	—	—
Any other individual impurity	—	1.0	0.10
Total impurities	—	—	0.5

[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.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store between 20° and 25°.
- **Labeling:** Label it to indicate that the Chewable Tablets are to be chewed before swallowing.

• **USP Reference Standards ⟨11⟩**

USP Loratadine RS

USP Loratadine Related Compound A RS

8-Chloro-5,6-dihydro-11-(piperidin-4-ylidene)-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine.

$C_{19}H_{19}ClN_2$ 310.82

USP Loratadine Related Compound B RS

8-Chloro-5,6-dihydro-11-(*N*-methylpiperidin-4-ylidene)-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine.

$C_{20}H_{21}ClN_2$ 324.85

USP Loratadine Related Compound C RS

8-Chloro-5,6-dihydro-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridin-11-one.

$C_{14}H_{10}ClNO$ 243.69

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

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

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