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Loratadine Oral Solution

DEFINITION
Loratadine Oral Solution contains NLT 94.0% and NMT 105.0% 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: 6.8 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.0 ± 0.1.

Mobile phase: Acetonitrile and *Buffer* (3:7)

Diluent: Acetonitrile and water (3:7)

Internal standard solution: 0.3 mg/mL of USP Butylparaben RS in *Diluent*

Standard stock solution: 1.0 mg/mL of USP Loratadine RS in acetonitrile

Standard solution: Transfer 5.0 mL of *Internal standard solution*, 5.0 mL of *Standard stock solution*, and 12 mL of water into a 50-mL volumetric flask. Dilute with *Diluent* to volume.

Sample solution: Transfer a portion of Oral Solution, nominally equivalent to 5 mg of loratadine, into a 50-mL volumetric flask. Pipet 5.0 mL of *Internal standard solution* into the flask, and dilute with *Diluent* 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: 3.9-mm × 30-cm; 10-µm packing L11

Column temperature: 20°–30°

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for butylparaben and loratadine are about 0.78 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.9 between loratadine and butylparaben

Tailing factor: NMT 1.6 for the loratadine and butylparaben peaks

Relative standard deviation: NMT 2%

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 Oral Solution taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of loratadine to the internal standard from the *Sample solution*

R_S = peak response ratio of loratadine to the internal standard 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: 94.0%–105.0%

PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirements

IMPURITIES

• **Organic Impurities**

Mobile phase: 4.3 g/L of sodium dodecyl sulfate in a mixture of acetonitrile and water (1:1). Adjust with phosphoric acid to a pH of 2.6 ± 0.1.

Diluent: *Mobile phase* and water (2:1)

System suitability solution 1: 2 µg/mL of USP Loratadine RS in *Diluent*

System suitability solution 2: 0.2 µg/mL of USP Loratadine RS in *Diluent* from *System suitability solution 1*

System suitability solution 3: Transfer an amount of Oral Solution, equivalent to 20 mg of loratadine, into a screw-cap glass container. Add 1 mL of 3% aqueous hydrogen peroxide and mix. Cap and heat at 65° for 18–24 h. Allow to cool to room temperature and then dilute 5 mL of the resulting solution with *Diluent* to 25 mL.

Sample solution: Nominally 0.2 mg/mL of loratadine from a volume of Oral Solution 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°–40°

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution 1*, *System suitability solution 2*, and *System suitability solution 3*

[Note—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between loratadine and 2-hydroxymethyl loratadine, *System suitability solution 3*

Tailing factor: 0.7–1.1, *System suitability solution 1*

Relative standard deviation: NMT 10%, *System suitability solution 2*

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual impurity in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each individual impurity in the *Sample solution*

r_T = sum of all the peak responses in the *Sample solution*, excluding excipient peaks

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
4-Hydroxymethyl loratadine[a]	0.70	0.3
2-Hydroxymethyl loratadine[b]	0.84	0.3
Loratadine	1.0	—
Any other individual impurity	—	0.2
Total impurities	—	0.5

[a] Ethyl 4-[8-chloro-5,6-dihydro-4-(hydroxymethyl)-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridin-11-ylidene]-1-piperidinecarboxylate.

[b] Ethyl 4-[8-chloro-5,6-dihydro-2-(hydroxymethyl)-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridin-11-ylidene]-1-piperidinecarboxylate.

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^2 cfu/mL, and the total combined molds and yeasts count is NMT 5×10^1 cfu/mL. It meets the requirements for the absence of *Salmonella* species and *Escherichia coli*.

• **pH ⟨791⟩:** 2.2–3.1

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store between 2° and 25°.

• **USP Reference Standards ⟨11⟩**

USP Butylparaben RS

USP Loratadine RS

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

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

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