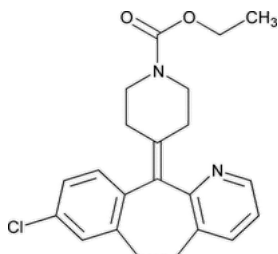


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Loratadine



$C_{22}H_{23}ClN_2O_2$ 382.88

1-Piperidinecarboxylic acid, 4-(8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)-, ethyl ester;

Ethyl 4-(8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)-1-piperidinecarboxylate CAS RN®: 79794-75-5; UNII: 7AJ03B07QN.

DEFINITION

Loratadine contains NLT 98.5% and NMT 101.0% of loratadine ($C_{22}H_{23}ClN_2O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)
- **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

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 to 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 an apparent pH of 7.2.

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.

Standard solution: 0.4 mg/mL of [USP Loratadine RS](#) in *Diluent*

Sample solution: 0.4 mg/mL of Loratadine 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

Column temperature: 25°–35°

Flow rate: 1 mL/min

Injection volume: 15 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of loratadine ($C_{22}H_{23}ClN_2O_2$) in the portion of Loratadine 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 = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES, PROCEDURE 1**

[NOTE—On the basis of the synthetic route, perform either *Procedure 1* or *Procedure 2*. *Procedure 2* is recommended if 4,8-dichloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-one is a potential related compound.]

Mobile phase and Diluent: Proceed as directed in the Assay.

Standard solution: 0.8 µg/mL of [USP Loratadine RS](#) in *Diluent*

Sample solution: 0.4 mg/mL of Loratadine 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

Column temperature: 25°–35°

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 4.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (1/F) \times 100$$

r_u = peak area of each impurity from the *Sample solution*

r_s = peak area of loratadine from the *Standard solution*

C_s = concentration of [USP Loratadine RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Loratadine in the *Sample solution* (mg/mL)

F = relative response factor as listed in [Table 1](#)

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Fluoroloratadine ^a	0.79	0.25	0.2
Loratadine	1.0	—	—
Any other individual impurity	—	1.0	0.1
Total impurities	—	—	0.3

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

• **ORGANIC IMPURITIES, PROCEDURE 2**

Solution A: Dissolve 0.96 g of 1-pentanesulfonic acid sodium salt in 900 mL of water. Adjust with phosphoric acid solution (1 in 10) to a pH of 3.00 ± 0.05, and dilute with water to 1 L.

Solution B: Acetonitrile



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