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Olopatadine Hydrochloride Ophthalmic Solution

DEFINITION

Olopatadine Hydrochloride Ophthalmic Solution is a sterile aqueous solution of Olopatadine Hydrochloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of olopatadine ($C_{21}H_{23}NO_3$). It may contain suitable antimicrobial agents.

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 in the range of 270–370 nm of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Protect all solutions containing olopatadine hydrochloride from light.

Buffer: Dissolve 13.6 g of [monobasic potassium phosphate](#) in 1 L of water, add 1 mL of [triethylamine](#), and mix. Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (28:72)

Standard solution: 0.1 mg/mL of [USP Olopatadine Hydrochloride RS](#) in *Mobile phase*

Sample solution: Nominally equivalent to 0.1 mg/mL of olopatadine in *Mobile phase*, from Ophthalmic Solution

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 299 nm or diode array. [NOTE—Use a diode array detector to perform the *Identification B* test.]

Column: 4.6-mm × 15-cm; 5-μm packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 30 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of olopatadine ($C_{21}H_{23}NO_3$) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Olopatadine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of olopatadine, 337.41

M_{r2} = molecular weight of olopatadine hydrochloride, 373.87

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• LIMIT OF EARLY ELUTING IMPURITIES

Protect all solutions containing olopatadine hydrochloride from light.

Mobile phase: Prepare as directed in the Assay.

System suitability solution: 0.2 mg/mL of [USP Olopatadine Hydrochloride RS](#) and 0.02 mg/mL of [USP Olopatadine Related Compound B RS](#) in *Mobile phase*

Standard solution: 0.2 mg/mL of [USP Olopatadine Hydrochloride RS](#) in *Mobile phase*

Sample solution: Equivalent to 0.2 mg/mL of olopatadine in *Mobile phase*, from Ophthalmic Solution

Blank solution: *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 299 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 30 μL

Run time: At least 1.6 times the retention time of the major peak

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between olopatadine and olopatadine related compound B, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times (1/F) \times 100$$

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

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

C_S = concentration of [USP Olopatadine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of olopatadine, 337.41

M_{r2} = molecular weight of olopatadine hydrochloride, 373.87

F = relative response factor for each individual impurity (see [Table 1](#))

Acceptance criteria: See [Table 1](#). Disregard any peaks corresponding to those of the *Blank solution* and any peaks with a relative retention time, measured with respect to olopatadine, greater than 1.5. Disregard any peak less than 0.1%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Olopatadine <i>E</i> -isomer ^a	0.7	1.3	0.5
Olopatadine	1.0	—	—
Olopatadine related compound B	1.2	1.0	—