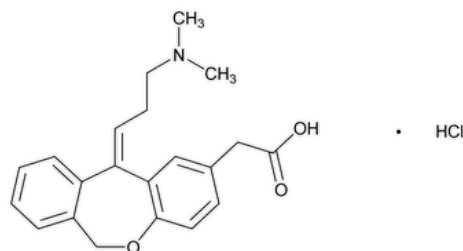


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Olopatadine Hydrochloride



$C_{21}H_{23}NO_3 \cdot HCl$ 373.87

Dibenz[b,e]oxepin-2-acetic acid, 11-[3-(dimethylamino)propylidene]-6,11-dihydro-, hydrochloride, (Z)-;

11-[(Z)-3-(Dimethylamino)propylidene]-6,11-dihydrodibenzo[b,e]oxepin-2-acetic acid, hydrochloride CAS RN®: 140462-76-6; UNII: 2XG66W44KF.

DEFINITION

Olopatadine Hydrochloride contains NLT 98.0% and NMT 102.0% of olopatadine hydrochloride ($C_{21}H_{23}NO_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197K ▲ (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.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chloride](#): Meets the requirements

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: 0.1 mg/mL of Olopatadine Hydrochloride in *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

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of olopatadine hydrochloride ($C_{21}H_{23}NO_3 \cdot HCl$) in the portion of Olopatadine Hydrochloride 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 Olopatadine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Olopatadine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

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

• **ORGANIC 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*

Sample solution: 0.2 mg/mL of Olopatadine Hydrochloride in *Mobile phase*

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 2.5 times the retention time of the major peak

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for olopatadine and olopatadine related compound B are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between olopatadine and olopatadine related compound B

Relative standard deviation: NMT 2.0%, olopatadine peak

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Olopatadine Hydrochloride taken:

$$\text{Result} = (r_U/r_T) \times (1/F) \times 100$$

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

r_T = sum of all the peak responses from the *Sample solution*

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

Acceptance criteria

Individual impurities: See [Table 1](#). Disregard any peaks corresponding to those of the *Blank solution*, and any peak less than 0.05%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
α-Hydroxy olopatadine ^a	0.4	1.0	0.2
Olopatadine <i>E</i> -isomer ^b	0.7	1.3	0.1