

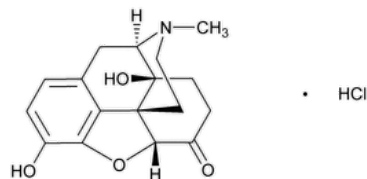
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Oxymorphone Hydrochloride

Change to read:

▲



▲ (USP 1-Aug-2023)

$C_{17}H_{19}NO_4 \cdot HCl$ 337.80

Morphinan-6-one, 4,5-epoxy-3,14-dihydroxy-17-methyl-, hydrochloride, (5 α)-;

4,5 α -Epoxy-3,14-dihydroxy-17-methylmorphinan-6-one hydrochloride CAS RN®: 357-07-3; UNII: 5Y2EI94NBC.

DEFINITION

Oxymorphone Hydrochloride contains NLT 97.0% and NMT 102.0% of oxymorphone hydrochloride ($C_{17}H_{19}NO_4 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)

Sample solution: Dissolve about 250 mg of Oxymorphone Hydrochloride in 25 mL of [water](#), and render the solution alkaline with a saturated solution of [sodium bicarbonate](#). Extract the liberated oxymorphone with two 15-mL portions of [chloroform](#). ▲ (USP 1-Aug-2023) Acidify the aqueous phase with 2 N [nitric acid](#).

Acceptance criteria: Meets the requirements

Change to read:

- **B.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K or 197A

Standard: Dissolve 20 mg of [USP Oxymorphone RS](#) with about 10 mL of [ethyl acetate](#). Evaporate to dryness under ambient conditions.

Sample: Dissolve about 20 mg of Oxymorphone Hydrochloride in 5 mL of [water](#). Render the solution alkaline with 5 mL of saturated [sodium bicarbonate](#) solution. Transfer the solution to a separating funnel and extract the oxymorphone with 10 mL of [ethyl acetate](#). Evaporate the extract to dryness under ambient conditions over molecular sieves.

Acceptance criteria: Meets the requirements ▲ (USP 1-Aug-2023)

Change to read:

- **C.** ▲ The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Aug-2023)

Delete the following:

- ▲ **D.** ▲ (USP 1-Aug-2023)

ASSAY

Change to read:

• PROCEDURE

▲ **Solution A:** 2.34 g/L of [octane sulfonic acid sodium salt, monohydrate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.2.

Solution B: [Acetonitrile](#) and [methanol](#) (40:60)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	90	10
2.0	90	10
14.0	80	20
25.0	60	40
25.1	1.5	98.5
29.0	1.5	98.5
29.1	90	10
35.0	90	10

Diluent: [Methanol](#) and *Solution A* (20:80)

Standard solution: 0.13 mg/mL of [USP Oxymorphone RS](#) in *Diluent*

Sample solution: 0.15 mg/mL of Oxymorphone Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 3-mm × 15-cm; 2.7-μm packing [L1](#)

Column temperature: 45°

Flow rate: 0.8 mL/min

Injection volume: 10 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 oxymorphone hydrochloride ($C_{17}H_{19}NO_4 \cdot HCl$) in the portion of Oxymorphone Hydrochloride taken:

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

r_U = peak response of oxymorphone from the *Sample solution*

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

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

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

M_{r1} = molecular weight of oxymorphone hydrochloride, 337.80

M_{r2} = molecular weight of oxymorphone, 301.34

▲ (USP 1-Aug-2023)

Acceptance criteria: 97.0%–102.0% on the dried basis