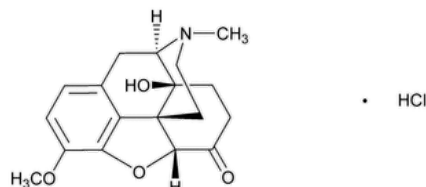


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-80B6FCDA-EE81-48B9-97FC-461200692834_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M59510_03_01
 DOI Ref: l1ybq

© 2025 USPC
 Do not distribute

Oxycodone Hydrochloride



$C_{18}H_{21}NO_4 \cdot HCl$ 351.82

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

4,5 α -Epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride CAS RN[®]: 124-90-3; UNII: C1ENJ2TE6C.

DEFINITION

Oxycodone Hydrochloride contains NLT 97.0% and NMT 103.0% of oxycodone hydrochloride ($C_{18}H_{21}NO_4 \cdot HCl$), calculated on the anhydrous, solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** ▲ **SPECTROSCOPIC IDENTIFICATION TESTS (197).**, *Infrared Spectroscopy*: 197A or 197K ▲ (CN 1-May-2020)

Sample: Dissolve 250 mg of Oxycodone Hydrochloride in 25 mL of [water](#). Render 25 mL of the resulting solution with 6 N [ammonium hydroxide](#). Allow the mixture to stand until a precipitate is formed. Filter, wash the precipitate with 50 mL of cold [water](#), and dry at 105° for 2 h.

Acceptance criteria: Meets the requirements

- **B.** The retention time of the oxycodone peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: 0.005 M [sodium 1-hexanesulfonate](#), [methanol](#), [triethylamine](#), and [phosphoric acid](#) (900:100:2:5). Adjust with 50% [sodium hydroxide](#) solution to a pH of 2.5 $\pm$ 0.1 and filter.

System suitability solution: 13 μ g/mL of [USP Codeine Phosphate RS](#) and 9 μ g/mL of [USP Oxycodone RS](#) in *Mobile phase*

Standard solution: 0.9 mg/mL of [USP Oxycodone RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Oxycodone Hydrochloride in *Mobile phase*. [NOTE—Pass a portion of this solution through a filter of 0.5- μ m or finer pore size, and use the filtrate as the *Sample solution*.]

Chromatographic system

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

Mode: LC

Detector: UV 206 nm

Column: 3.9-mm $\times$ 15-cm; 4- μ m packing [L7](#)

Column temperature: 50°

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

Run time: NLT 2 times the retention time of oxycodone

System suitability

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

[NOTE—The relative retention times for codeine and oxycodone are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between codeine and oxycodone, *System suitability solution*

Tailing factor: 0.75–1.25, *Standard solution*

Relative standard deviation: NMT 1.10%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxycodone hydrochloride ($C_{18}H_{21}NO_4 \cdot HCl$) in the portion of Oxycodone Hydrochloride 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 Oxycodone RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of oxycodone hydrochloride, 351.82

M_{r2} = molecular weight of oxycodone base, 315.37

Acceptance criteria: 97.0%–103.0% on the anhydrous, solvent-free basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.05%

[NOTE—Use of sulfuric acid is omitted.]

[NOTE—On the basis of the synthetic route, perform either *Procedure 1* or *Procedure 2*. *Procedure 1* is recommended if 8β-hydroxyoxycodone (7,8-dihydro-8β-14-dihydroxycodeinone) is a potential impurity.]

- **ORGANIC IMPURITIES, PROCEDURE 1**

Mobile phase, System suitability solution, Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

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

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

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

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

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

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Oxymorphone	0.31	0.15
Noroxymorphone ^a	0.33	0.15
10-Hydroxyoxycodone ^b	0.53	0.15
6-α Oxycodol ^c	0.67	0.25
8β-Hydroxyoxycodone (7,8-dihydro-8β-14-dihydroxycodeinone) ^d	0.71	0.15



Documents

Document Sharing Hub