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Oxycodone Hydrochloride Tablets

DEFINITION
Oxycodone Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of oxycodone hydrochloride ($C_{18}H_{21}NO_4 \cdot HCl$).

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*.

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Dec-2023)

ASSAY
Change to read:
• **Procedure**

▲**Solution A:** Dissolve 3.48 g of dibasic potassium phosphate in 1 L of water. Adjust with phosphoric acid to a pH of 6.7.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
1	90	10
12	50	50
12.1	90	10
15	90	10

Diluent: 0.1% (v/v) phosphoric acid in water

Standard solution: 0.1 mg/mL of USP Oxycodone Hydrochloride RS in *Diluent*

Sample solution: Nominally 0.1 mg/mL of oxycodone hydrochloride in *Diluent*, prepared as follows. Transfer a quantity of finely powdered Tablets (NLT 20), nominally equivalent to 5 mg of oxycodone hydrochloride, to a 50-mL volumetric flask. Add 40 mL of *Diluent*, sonicate for about 5 min. Cool to room temperature, and agitate on a mechanical shaker for about 15 min. Dilute with *Diluent* to volume. Centrifuge and use the clear supernatant.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)
Mode: LC
Detector: UV 206 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.
Column: 4.6-mm × 10-cm; 3-µm packing L1
Column temperature: 45°
Flow rate: 0.7 mL/min
Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxycodone hydrochloride ($C_{18}H_{21}NO_4 \cdot HCl$) in the portion of Tablets taken:

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

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

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

C_S = concentration of USP Oxycodone Hydrochloride RS in the *Standard solution* (mg/mL)

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

▲ (USP 1-Dec-2023)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Medium: Water; 500 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: A known concentration of ▲USP Oxycodone Hydrochloride RS in water▲ (USP 1-Dec-2023)

Sample solution: A portion of the solution under test. Dilute with *Medium* as needed.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: Maximum at about 225 nm

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of oxycodone hydrochloride ($C_{18}H_{21}NO_4 \cdot HCl$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times D \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Oxycodone Hydrochloride RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

D = dilution factor of the *Sample solution*, if applicable

▲ (USP 1-Dec-2023)

Tolerances: NLT 70% (Q) of the labeled amount of oxycodone hydrochloride ($C_{18}H_{21}NO_4 \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

Add the following:

▲IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability solution: 1.0 mg/mL of USP Oxycodone Hydrochloride RS, 0.01 mg/mL each of USP Hydrocodone RS and USP Oxycodone Related Compound A RS in *Diluent*

Standard solution: 2 µg/mL each of USP Oxycodone Hydrochloride RS and USP Oxycodone Related Compound B RS in *Diluent*

Sensitivity solution: 1 µg/mL each of USP Oxycodone Hydrochloride RS and USP Oxycodone Related Compound B RS in *Diluent* from *Standard solution*

Sample solution: Nominally 1.0 mg/mL of oxycodone hydrochloride in *Diluent*, prepared as follows. Transfer a quantity of finely powdered Tablets (NLT 20), nominally equivalent to 20 mg of oxycodone hydrochloride, to a 20-mL volumetric flask. Add 15 mL of *Diluent*, and sonicate for about 5 min. Cool to room temperature, and agitate on a mechanical shaker for about 15 min. Dilute with *Diluent* to volume. Centrifuge and use the clear supernatant.

System suitability

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

[NOTE—The relative retention times for hydrocodone and oxycodone related compound A are about 1.2 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 1.5 between hydrocodone and oxycodone related compound A, *System suitability solution*

Relative standard deviation: NMT 5.0% for oxycodone and oxycodone related compound B, *Standard solution*

Signal-to-noise ratio: NLT 10 for oxycodone and oxycodone related compound B, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxycodone related compound B in the portion of Tablets taken:

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

r_U = peak response of oxycodone related compound B from the *Sample solution*

r_S = peak response of oxycodone related compound B from the *Standard solution*

C_S = concentration of USP Oxycodone Related Compound B RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of oxycodone hydrochloride in the *Sample solution* (µg/mL)

Calculate the percentage of any unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of any unspecified degradation product from the *Sample solution*

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

C_S = concentration of USP Oxycodone Hydrochloride RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of oxycodone hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: See *Table 2*. The reporting threshold is 0.1%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Oxycodone related compound B	0.8	0.2
Oxycodone	1.0	—
Any unspecified degradation product	—	0.2
Total degradation products	—	0.5

▲ (USP 1-Dec-2023)

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight, light-resistant containers. ▲Store at controlled room temperature.▲ (USP 1-Dec-2023)

Change to read:

• **USP Reference Standards** ⟨11⟩

▲ USP Hydrocodone RS

4,5α-Epoxy-3-methoxy-17-methylmorphinan-6-one.

$C_{18}H_{21}NO_3$ 299.37

USP Oxycodone Hydrochloride RS

USP Oxycodone Related Compound A RS

4,5α-Epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-7-ene-6-one.

$C_{18}H_{19}NO_4$ 313.35

USP Oxycodone Related Compound B RS

4,5α-Epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one *N*-oxide.

$C_{18}H_{21}NO_5$ 331.37▲ (USP 1-Dec-2023)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
OXYCODONE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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