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Oxycodone Hydrochloride Extended-Release Tablets

DEFINITION

Oxycodone Hydrochloride Extended-Release 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-2021)

ASSAY

Change to read:

• PROCEDURE

▲ **Buffer solution:** 7.8 g/L of [potassium phosphate, monobasic](#) in [water](#), adjusted with [phosphoric acid](#) to a pH of 3.0

Mobile phase: [Acetonitrile](#) and *Buffer solution* (10:90)

Diluent: [Acetonitrile](#) and [simulated gastric fluid TS](#) without enzyme (10:20)

0.85% phosphoric acid: 10 mL/L of [phosphoric acid](#) in [water](#)

Standard stock solution: 0.9 mg/mL of [USP Oxycodone RS](#) in 0.85% phosphoric acid

Standard solution: 0.09 mg/mL of [USP Oxycodone RS](#) in *Diluent* from the *Standard stock solution*

Sample stock solution: Nominally ($L/100$) mg/mL of oxycodone hydrochloride where L is the label claim in mg/Tablets. Transfer 10 Tablets into a 1000-mL volumetric flask, and add 900 mL of *Diluent*. Stir until the Tablets are completely dispersed. Dilute with *Diluent* to volume. Physically manipulate the Tablets as necessary to ensure complete dispersion within 24 h with stirring in *Diluent*. Protect this solution from light.

Sample solution: Nominally about 0.1 mg/mL of oxycodone hydrochloride in *Diluent* from the *Sample stock solution*. Pass through a suitable filter of 0.45- μ m pore size. For Tablets labeled to contain 10 mg, use the *Sample stock solution* directly.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm. For *Identification B*, use a diode array detector in the range of 200–350 nm.

Column: 3.0-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 60°

Flow rate: 1.0 mL/min

Injection volume: 10 μ L

Run time: NLT 1.4 times the retention time of oxycodone

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.7–1.2

Relative standard deviation: NMT 2.0%

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:

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

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 RS](#) in the *Standard solution* (mg/mL)

C_U = nominal 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, 315.36▲ (USP 1-Dec-2021)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#).

▲ **Medium:** [Simulated gastric fluid TS](#) without enzymes; 900 mL

Apparatus 1: 100 rpm. Include a stainless-steel spring across the underside of the top of each of the baskets to prevent Tablet adhesion to the underside of the top of the baskets during the test.

Times: 1, 4, and 12 h

0.85% phosphoric acid: 10 mL/L of [phosphoric acid](#) in [water](#)

Mobile phase: Transfer 28.0 g of [potassium phosphate, monobasic](#) into a 4-L flask, and dissolve with 3600 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0. Add 400 mL of [acetonitrile](#), and mix.

Standard stock solution: 0.9 mg/mL of [USP Oxycodone RS](#) in 0.85% phosphoric acid

Standard solution: Dilute the *Standard stock solution* with *Medium* to obtain a solution having a concentration of 0.009 mg/mL of [USP Oxycodone RS](#) for Tablets labeled to contain 10, 15, 20, 30, and 40 mg, and 0.063 mg/mL of [USP Oxycodone RS](#) for Tablets labeled to contain 60 and 80 mg.

Sample solution: Pass the solution under test through a suitable filter of 1.0- or 10-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 3.0-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 60°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

Run time: NLT 3.7 times the retention time of oxycodone

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.7–1.2

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of oxycodone hydrochloride ($C_{18}H_{21}NO_4 \cdot HCl$) in the sample withdrawn from the vessel at each time point (i):

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

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 RS](#) in the *Standard solution* (mg/mL)

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

M_{r2} = molecular weight of oxycodone base, 315.36