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Naltrexone Hydrochloride Tablets

DEFINITION

Naltrexone Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of naltrexone hydrochloride ($C_{20}H_{23}NO_4 \cdot HCl$).

IDENTIFICATION

Change to read:

• **▲A.▲** (USP 1-Aug-2019) The retention time of the naltrexone 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 naltrexone peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2019)

ASSAY

Change to read:

• **Procedure**

Solution A: Dissolve about 1.08 g of sodium 1-octanesulfonate and about 23.8 g of sodium acetate in 800 mL of water. Add 1.0 mL of triethylamine and 200 mL of methanol, and adjust with glacial acetic acid to a pH of 6.5 ± 0.1.

Solution B: Dissolve about 1.08 g of sodium 1-octanesulfonate and about 23.8 g of sodium acetate in 400 mL of water. Add 1.0 mL of triethylamine and 600 mL of methanol, and adjust with glacial acetic acid to a pH of 6.5 ± 0.1.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
35	0	100
36	100	0
53	100	0

Standard solution: 2.25 mg/mL of USP Naltrexone RS prepared as follows. Transfer an amount of USP Naltrexone RS to a suitable volumetric flask, add 15% of the final volume of methanol and 6% of the final volume of 0.1 N hydrochloric acid, and dissolve by swirling. Dilute with 0.1 M phosphoric acid to volume.

System suitability stock solution: 0.3 mg/mL of USP Naltrexone Related Compound A RS prepared as follows. Transfer a quantity of USP Naltrexone Related Compound A RS to a suitable volumetric flask, add 30% of the final volume of methanol, and dissolve by swirling. Dilute with 0.1 M phosphoric acid to volume.

System suitability solution: 1.125 mg/mL of USP Naltrexone RS and 0.015 mg/mL of USP Naltrexone Related Compound A RS prepared as follows. Transfer suitable volumes of *System suitability stock solution* and *Standard solution* to an adequate volumetric flask, and dilute with 0.1 M phosphoric acid to volume.

Sample solution: Nominally 2.5 mg/mL of naltrexone hydrochloride in 0.1 M phosphoric acid prepared as follows. Transfer NLT 20 Tablets to a tared container, and determine the average Tablet weight. Grind the Tablets to a homogeneous mixture. Transfer a portion of the powdered Tablets, equivalent to 250 mg of naltrexone hydrochloride, to a 100-mL volumetric flask. Add 80 mL of 0.1 M phosphoric acid and shake or sonicate for at least 30 min. Dilute with 0.1 M phosphoric acid to volume, mix, and filter.

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 200–400 nm.▲ (USP 1-Aug-2019)

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Column: 3.9-mm × 15-cm; ▲4-µm▲ (USP 1-Aug-2019) packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: ▲*Standard solution* and▲ (USP 1-Aug-2019) *System suitability solution*

[NOTE—The relative retention times for ▲naltrexone and naltrexone related compound A are 1.0 and 1.26, respectively.▲ (USP 1-Aug-2019)]

Suitability requirements

Resolution: NLT 2.0 between naltrexone and naltrexone related compound A, ▲*System suitability solution*▲ (USP 1-Aug-2019)

Tailing factor: NMT 1.4, ▲*Standard solution*▲ (USP 1-Aug-2019)

Relative standard deviation: NMT 2.0%, ▲*Standard solution*▲ (USP 1-Aug-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of naltrexone hydrochloride ($C_{20}H_{23}NO_4 \cdot HCl$) 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 naltrexone from the *Sample solution*

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

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

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

M_{r1} = molecular weight of naltrexone hydrochloride, 377.86

M_{r2} = molecular weight of naltrexone, ▲341.41▲ (USP 1-Aug-2019)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **DISSOLUTION** ⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 60 min

Standard solution: A known concentration of USP Naltrexone RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Buffer: 0.05 M phosphate buffer (Dissolve 7.0 g of monobasic sodium phosphate in 1 L of water.)

Mobile phase: Mix 600 mL of *Buffer*, 1.1 g of sodium 1-octane sulfonate monohydrate, and 400 mL of methanol. Adjust with dilute sodium hydroxide to a pH of 6.7 ± 0.05.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 15-cm; packing L1

Temperature: 45°

Flow rate: 1 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of naltrexone hydrochloride ($C_{20}H_{23}NO_4 \cdot HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

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

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

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

V = volume of *Medium*, 900 mL

M_{r1} = molecular weight of naltrexone hydrochloride, 377.86

M_{r2} = molecular weight of naltrexone, 341.41

L = label claim (mg/Tablet)

▲ (USP 1-Aug-2019)

Tolerances: NLT 80% (*Q*) of the labeled amount of naltrexone hydrochloride ($C_{20}H_{23}NO_4 \cdot HCl$) is dissolved.

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

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers. ▲Store at controlled room temperature.▲ (USP 1-Aug-2019)

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Naltrexone RS

USP Naltrexone Related Compound A RS

▲17-(But-3-en-1-yl)-4,5α-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride.▲ (USP 1-Aug-2019)

$C_{20}H_{23}NO_4 \cdot HCl$ ▲377.86▲ (USP 1-Aug-2019)

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

Topic/Question	Contact	Expert Committee
NALTREXONE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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