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Add the following:

▲Naltrexone Hydrochloride Compounded Cream

DEFINITION

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

Prepare Naltrexone Hydrochloride Compounded Cream 10 mg/g as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Naltrexone hydrochloride	1 g
Hydrolyzed hyaluronic acid	0.5 g
Glycerin	5 g
XemaTop Base[a]	93.5 g

[a] PCCA, Houston, TX.

In an appropriately sized electronic mortar and pestle container, add *Naltrexone hydrochloride, Hydrolyzed hyaluronic acid*, and *Glycerin*. Add *XemaTop Base*. Mix the mixture with an electronic mortar and pestle for 2 min on a speed of about 1400–1450 rpm. Process through an ointment mill once at the middle setting and once at the finest setting to reduce the particle size of the active ingredient and reduce air content of the preparation. Return the mixture to the electronic mortar and pestle and mix again for 1 min on the low setting.

ASSAY

• **Procedure**

Solution A: 0.1% trifluoroacetic acid in water

Solution B: 0.1% trifluoroacetic acid in acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
1.0	80	20
3.5	10	90
3.6	95	5
4.5	95	5

Standard solution: Transfer 100 mg of USP Naltrexone RS to a 100-mL volumetric flask and dilute with water to volume. Sonicate for 15 s. Transfer 25 mL of the resultant solution to a 1000-mL volumetric flask and dilute with methanol to volume.

Sample solution: Transfer 0.5 g of Cream into a 50-mL centrifuge tube, add 2 mL of water, and vortex for 30 s. Sonicate for 1 min and vortex for 30 s. Add 17.5 mL of methanol to the mixture and vortex for 30 s. Sonicate the mixture for 2 min and vortex for 30 s. Sonicate the

mixture again for 2 min and vortex for 30 s. Centrifuge the mixture for 20 min at 6000 rpm. Transfer 1 mL of the supernatant to a 10-mL volumetric flask and dilute with methanol to volume. Centrifuge for 10 min at 14×10^3 rpm.

Chromatographic system

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

Mode: LC

Detection: UV 225 nm

Column: 2.1-mm × 5-cm; 1.7-µm packing L1

Temperatures

Autosampler: 8°

Column: 65°

Flow rate: 1 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for naltrexone hydrochloride is about 0.82 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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 Cream 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/g)

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

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

M_{r2} = molecular weight of naltrexone, 341.41

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 4.4–5.4
- **Viscosity—Rotational Methods ⟨912⟩:** 350–3500 mPa · s

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.
- **Beyond-Use Date:** NMT 180 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator.
- **Labeling:** Label it to indicate that it is for external use only and to state the *Beyond-Use Date*.
- **USP Reference Standards ⟨11⟩**

USP Naltrexone RS▲ (USP 1-Dec-2021)

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

Topic/Question	Contact	Expert Committee
NALTREXONE HYDROCHLORIDE COMPOUNDED CREAM	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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