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Naftifine Hydrochloride Cream

DEFINITION

Naftifine Hydrochloride Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of naftifine hydrochloride ($C_{21}H_{21}N \cdot HCl$) in a water-miscible base.

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*.

ASSAY

• **Procedure**

Mobile phase: *n*-Hexane, alcohol, dimethylformamide, and formic acid (200:60:40:2). Cover tightly with a moisture-proof film, and allow to stand for 12 h at room temperature.

Standard solution: 0.2 mg/mL of USP Naftifine Hydrochloride RS in *Mobile phase*

Sample solution: Transfer 1000 mg of Cream to a 100-mL volumetric flask. Dissolve in 60 mL of methanol, mix vigorously for 2 min, and dilute with methanol to volume. Heat at 45° for 5 min, and cool to room temperature.

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 25-cm; 5-µm packing L3

Flow rate: 2 mL/min

Injection volume: 15 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of naftifine hydrochloride ($C_{21}H_{21}N \cdot HCl$) in the portion of Cream taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Organisms ⟨62⟩:** It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

• **pH ⟨791⟩:** 4.0–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

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USP Naftifine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
NAFTIFINE HYDROCHLORIDE CREAM	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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