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Naftifine Hydrochloride Gel

DEFINITION

Naftifine Hydrochloride Gel 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 Gel 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: 20 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 Gel 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

• CONTENT OF ALCOHOL

Internal standard solution: Transfer 10.0 mL of *n*-propyl alcohol to a 200-mL volumetric flask, and dilute with water to volume.

Standard stock solution: 10.0 mg/mL of alcohol

Standard solution: Transfer 3.0 mL of *Internal standard solution* to a 10-mL volumetric flask, and dilute with *Standard stock solution* to volume.

Sample solution: Transfer 250 mg of Gel to a suitable container. Add 14.0 mL of water and 6.0 mL of *Internal standard solution*, and shake for 15 min.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)**Mode:** GC**Detector:** Flame ionization**Column:** 3.2-mm × 1.5-m; 80- to 100-mesh support S3**Temperatures****Injector:** 200°**Column:** 170°**Detector:** 200°**Carrier gas:** Nitrogen**Flow rate:** 45 mL/min**Injection volume:** 1 µL**System suitability****Sample:** Standard solution**Suitability requirements****Resolution:** NLT 2.0 between alcohol and the internal standard**Capacity factor, *k'*:** 2.0–3.5 for alcohol and 6.0–8.0 for the internal standard**Tailing factor:** NMT 2.5**Relative standard deviation:** NMT 2.5%**Analysis****Samples:** Standard solution and Sample solutionCalculate the percentage of alcohol (C_2H_5OH) in the portion of Gel taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

 R_U = peak response ratio of alcohol to the internal standard from the Sample solution R_S = peak response ratio of alcohol to the internal standard from the Standard solution C_S = concentration of alcohol in the Standard solution (mg/mL) C_U = concentration of the Sample solution (mg/mL)**Acceptance criteria:** 40%–45%

- [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 \(791\)](#): 5.5–7.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Naftifine Hydrochloride RS](#)**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NAFTIFINE HYDROCHLORIDE GEL	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](#)**Most Recently Appeared In:**

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