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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 solution*

Calculate the percentage of alcohol (C<sub>2</sub>H<sub>5</sub>OH) 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	<a href="#">Documentary Standards Support</a>	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM12020 Small Molecules 1

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. Information currently unavailable

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