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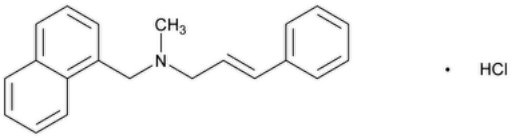
Naftifine Hydrochloride



$C_{21}H_{21}N \cdot HCl$ 323.86

1-Naphthalenemethanamine, *N*-methyl-*N*-(3-phenyl-2-propenyl)-, hydrochloride, (*E*)-;

(*E*)-*N*-Cinnamyl-*N*-methyl-1-naphthalenemethylamine hydrochloride CAS RN®: 65473-14-5; UNII: 25UR9N9041.

DEFINITION

Naftifine Hydrochloride contains NLT 99.0% and NMT 101.0% of naftifine hydrochloride ($C_{21}H_{21}N \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **B.** 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, absolute 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: 0.2 mg/mL of Naftifine Hydrochloride in *Mobile phase*

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 naftifine hydrochloride ($C_{21}H_{21}N \cdot HCl$) in the portion of Naftifine Hydrochloride 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 = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 99.0%–101.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

Mobile phase, Standard solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Naftifine Hydrochloride taken:

Result = $(r_U/r_T) \times 100$

r_U = peak response for each impurity

r_T = sum of all the peak responses

Acceptance criteria

Individual impurity: NMT 0.1%

Total impurities: NMT 1.0%

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry over phosphorus pentoxide at 105° for 4 h.

Acceptance criteria: NMT 0.5%

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	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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