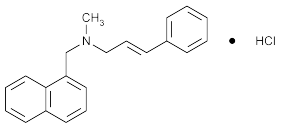
obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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 [65473-14-5].

» Naftifine Hydrochloride contains not less than 99.0 percent and not more than 101.0 percent of $C_{21}H_{21}N \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Naftifine Hydrochloride RS

Identification, *Infrared Absorption* ⟨197K⟩.

Melting range ⟨741⟩: between 175° and 179°.

Loss on drying ⟨731⟩**—**Dry over phosphorus pentoxide at 105° for 4 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Heavy metals, *Method II* ⟨231⟩: 0.001%.

Chromatographic purity—

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay*.

Test preparation—Use the *Assay preparation*.

Procedure—Inject a volume (about 15 µL) of the *Test preparation* into the chromatograph, record the chromatogram, and measure the peak responses. Calculate the percentage of each impurity in the portion of Naftifine Hydrochloride taken by the formula:

$$100(r_i / r_S)$$

in which r_i is the peak response for each impurity, and r_S is the sum of the responses of all of the peaks: not more than 0.1% of any individual impurity is found, and the sum of all impurities is not more than 1.0%.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of *n*-hexane, alcohol, dimethylformamide, and formic acid (200:60:40:2), cover tightly with a moisture-proof film, and allow to stand for 12 hours at room temperature. Make adjustments, if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Naftifine Hydrochloride RS in *Mobile phase*, and dilute quantitatively, and stepwise, if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Transfer about 10 mg of Naftifine Hydrochloride, accurately weighed, to a 50-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 270-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L3. The flow rate is about 2.0 mL per minute.

Procedure—Separately inject equal volumes (about 15 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{21}H_{21}N \cdot HCl$ in the portion of Naftifine Hydrochloride taken by the formula:

$$50C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Naftifine Hydrochloride RS in the *Standard preparation*, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Naftifine Hydrochloride Cream

» Naftifine Hydrochloride Cream contains not less than 90.0 percent and not more than 110.0 percent of Naftifine Hydrochloride ($C_{21}H_{21}N \cdot HCl$) in a water-miscible base.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Naftifine Hydrochloride RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* as obtained in the *Assay*.

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Minimum fill ⟨755⟩**:** meets the requirements.

pH ⟨791⟩**:** between 4.0 and 6.0.

Assay—

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Naftifine Hydrochloride*.

Assay preparation—Transfer about 1000 mg of Cream, accurately weighed, to a 100-mL volumetric flask, dissolve in 60 mL of methanol, mix vigorously for 2 minutes, and dilute with methanol to volume. Heat at 45° for 5 minutes, and cool to room temperature.

Procedure—Separately inject equal volumes (about 15 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{21}H_{21}N \cdot HCl$ in the portion of Cream taken by the formula:

$$100C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Naftifine Hydrochloride RS in the *Standard preparation,* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Naftifine Hydrochloride Gel

» Naftifine Hydrochloride Gel contains not less than 90.0 percent and not more than 110.0 percent of Naftifine Hydrochloride ($C_{21}H_{21}N \cdot HCl$) in a water-miscible base.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Naftifine Hydrochloride RS