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Tolnaftate Topical Aerosol

DEFINITION

Tolnaftate Topical Aerosol is a suspension of powder in suitable propellants in a pressurized container. The powder contains NLT 90.0% and NMT 110.0% of the labeled amount of tolnaftate ($C_{19}H_{17}NOS$).

IDENTIFICATION

Change to read:

• ▲**A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2024)

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2024)

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** Methanol and water (70:30). To each liter of the solution, add 1 mL of trifluoroacetic acid.

Solution B: Methanol and water (90:10). To each liter of the solution, add 1 mL of trifluoroacetic acid.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
12	100	0
30	0	100
33	0	100

Standard solution: 0.05 mg/mL of USP Tolnaftate RS in methanol

Sample solution: Nominally 0.05 mg/mL of tolnaftate prepared as follows. Press the actuator button gently to expel the volatile propellant fractions from the container and transfer the entire contents into a conical flask. Place the conical flask in an oven at 105° and heat to a constant weight to obtain a dry powder. Cool the flask and mix the dried powder thoroughly. Weigh and transfer a quantity equivalent to 1 mg of tolnaftate from the dried powder into a 20-mL volumetric flask, add 10 mL of methanol, shake for 1 h, and dilute with methanol to volume. Centrifuge at 8000 rpm for 10 min, pass a portion of the supernatant through a suitable filter of 0.45-µm pore size, and discard the first 2 mL.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing L1

Temperatures

Autosampler: 4°

Column: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tolnaftate ($C_{19}H_{17}NOS$) in the portion of Topical Aerosol taken:

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

r_U = peak response of tolnaftate from the *Sample solution*

r_S = peak response of tolnaftate from the *Standard solution*

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

C_U = nominal concentration of tolnaftate in the *Sample solution* (mg/mL)▲ (USP 1-May-2024)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Delete the following:

▲• **Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders—Performance Quality Tests ⟨601⟩**▲ (USP 1-May-2024)

Add the following:

▲• **Topical Aerosols ⟨603⟩, *Pressure Test*:** Meets the requirements▲ (USP 1-May-2024)

Add the following:

▲• **Minimum Fill ⟨755⟩:** Meets the requirements▲ (USP 1-May-2024)

Add the following:

▲• **Leak Rate ⟨604⟩:** Meets the requirements▲ (USP 1-May-2024)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, pressurized containers. Store at controlled room temperature, and avoid exposure to excessive heat.

• **USP Reference Standards ⟨11⟩**

USP Tolnaftate RS

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

Topic/Question	Contact	Expert Committee
TOLNAFTATE TOPICAL AEROSOL	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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