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Tolnaftate Cream

DEFINITION
Tolnaftate Cream 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 *Solution A*

Sample solution: Nominally 0.05 mg/mL of tolnaftate prepared as follows. Weigh and transfer a quantity of Cream equivalent of 2.5 mg of tolnaftate into a 50-mL volumetric flask and add 30 mL of *Solution A*. Vortex for 5 min and heat the flask in a water bath at 50° for 1.5 h. Cool to room temperature and dilute with *Solution A* to volume. Place the volumetric flask in the refrigerator for 30 min and centrifuge at 8000 rpm for 10 min at 4°. Pass a portion of the cold 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 Cream 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

• **Minimum Fill ⟨755⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **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 CREAM	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

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