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Tolnaftate Topical Solution

DEFINITION
Tolnaftate Topical Solution contains NLT 90.0% and NMT 115.0% of the labeled amount of tolinaftate (C₁₉H₁₇NOS).

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 tolinaftate from a suitable amount of Topical Solution in [methanol](#)

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 tolinaftate (C₁₉H₁₇NOS) in the portion of the Topical Solution taken:

Result = (r_U/r_S) × (C_S/C_U) × 100

- r_U = peak response of tolinaftate from the Sample solution
- r_S = peak response of tolinaftate from the Standard solution
- C_S = concentration of [USP Tolinaftate RS](#) in the Standard solution (mg/mL)
- C_U = nominal concentration of tolinaftate in the Sample solution (mg/mL)▲ (USP 1-May-2024)

Acceptance criteria: 90.0%–115.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS (11).**
[USP Tolinaftate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TOLNAFTATE TOPICAL SOLUTION	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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