Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Dec-2023
Document Type: USP Monographs
DocId: GUID-83512D19-8F87-4725-815A-8A569CD22CE5_2_en-US
DOI: https://doi.org/10.31003/USPNF_M84230_02_01
DOI Ref: tvo44

Tolnaftate Gel

(*This monograph has been updated to the current USP style. No revisions or changes to tests have been made.*)

DEFINITION

Tolnaftate Gel contains NLT 90.0% and NMT 110.0% of the labeled amount of tolnaftate ($C_{19}H_{17}NOS$).

IDENTIFICATION

• **A.**

Standard solution: 1 mg/mL of USP Tolnaftate RS in alcohol

Sample stock solution: Use the *Sample stock solution* prepared in the *Assay*.

Sample solution: Nominally 1 mg/mL of tolnaftate prepared as follows: Evaporate 10 mL of the *Sample stock solution* on a steam bath just to dryness, and dissolve the residue in 1 mL of alcohol.

Chromatographic system

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Mode: TLC

Absorbent: 0.25-mm layer of chromatographic silica gel mixture

Developing solvent system: Toluene

Application volume: 10 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. Allow the spots to dry and develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber and view under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot from the *Sample solution* corresponds to that from the *Standard solution*.

ASSAY

• **Procedure**

Standard solution: 10 µg/mL of USP Tolnaftate RS in chloroform

Sample stock solution: Nominally 0.1 mg/mL of tolnaftate prepared as follows. Transfer a portion of Gel, equivalent to 10 mg of tolnaftate, into a 250-mL separator containing 75 mL of chloroform. Wash the chloroform solution successively with two 25-mL portions of 0.1 N sodium hydroxide VS, two 25-mL portions of 0.1 N hydrochloric acid VS, and 25 mL of water. Transfer the chloroform layer to a 100-mL volumetric flask, and dilute with chloroform to volume. [Note—Reserve a 10-mL portion of this solution for *Identification A*.]

Sample solution: Nominally 10 µg/mL of tolnaftate in chloroform from the *Sample stock solution*

Instrumental conditions

Mode: UV

Analytical wavelength: 258 nm

Cell: 1 cm

Blank: Chloroform

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

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

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = nominal concentration of tolnaftate in the *Sample solution* (µg/mL)

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 GEL	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:
Pharmacopeial Forum: Volume No. Information currently unavailable

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