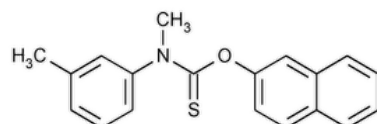


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-8FF91E7F-8F56-446B-A039-ADFAAAD110B9_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M84190_04_01
 DOI Ref: w2hyd

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Tolnaftate



$C_{19}H_{17}NOS$ 307.41

Carbamothioic acid, methyl(3-methylphenyl)-, O-2-naphthalenyl ester.

O-2-Naphthyl *m,N*-dimethylthiocarbamate CAS RN®: 2398-96-1; UNII: 06KB629TKV.

» Tolnaftate contains not less than 98.0 percent and not more than 102.0 percent of $C_{19}H_{17}NOS$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—

[USP Tolnaftate RS](#)

Identification—

Change to read:

A: ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-May-2020) ·

B: The UV absorption spectrum of the solution employed for measurement of absorbance in the Assay exhibits maxima and minima at the same wavelengths as that of a similar solution of [USP Tolnaftate RS](#), concomitantly measured.

C: Prepare a test solution by dissolving 10 mg in 10 mL of alcohol. Apply 10 µL of this test solution and 10 µL of a Standard solution of [USP Tolnaftate RS](#) in alcohol having a concentration of 1.0 mg per mL to a thin-layer chromatographic plate (see [Chromatography \(621\)](#)) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram, using toluene as the solvent system, until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, allow the solvent to evaporate, and view under short-wavelength UV light: the R_f value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

MELTING RANGE (741): between 110° and 113°.

LOSS ON DRYING (731)—Dry it in vacuum at 65° for 3 hours: it loses not more than 0.5% of its weight.

RESIDUE ON IGNITION (281): not more than 0.1%.

Assay—Dissolve about 50 mg of Tolnaftate, accurately weighed, in methanol, and dilute the solution quantitatively and stepwise with methanol to obtain a concentration of about 10 µg per mL. Dissolve an accurately weighed quantity of [USP Tolnaftate RS](#) in methanol, and dilute quantitatively and stepwise with methanol to obtain a Standard solution having a known concentration of about 10 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 258 nm, with a suitable spectrophotometer, using methanol as the blank. Calculate the quantity, in mg, of $C_{19}H_{17}NOS$ in the portion of Tolnaftate taken by the formula:

$$5C(A_u/A_s)$$

in which C is the concentration, in µg per mL, of [USP Tolnaftate RS](#) in the Standard solution, and A_u and A_s are the absorbances of the solution of Tolnaftate and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
TOLNAFTATE	Documentary Standards Support	SM12020 Small Molecules 1

Topic/Question	Contact	Expert Committee
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. 48(4)

Current DocID: GUID-8FF91E7F-8F56-446B-A039-ADFAAAD110B9_4_en-US

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