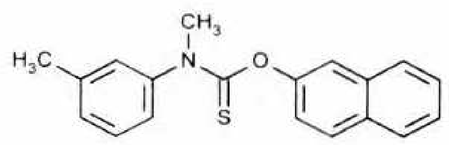
Tolnaftate



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

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

O-2-Naphthyl *m*,*N*-dimethylthiocarbanilate [*2398-96-1*].

» 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—

A: *Infrared Absorption* ⟨197K⟩.

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%.

Heavy metals, *Method II* ⟨231⟩: 0.002%.

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.