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Diethyltoluamide Topical Solution

DEFINITION

Diethyltoluamide Topical Solution is a solution of Diethyltoluamide in Alcohol or Isopropyl Alcohol. It contains NLT 92.0% and NMT 108.0% of the labeled amount of the *meta*-isomer of diethyltoluamide ($C_{12}H_{17}NO$). If it contains Alcohol, NLT 95.0% and NMT 105.0% of the labeled amount of alcohol (C_2H_5OH) is present.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197S**▲ (CN 1-May-2020)

Sample solution: Nominally 20 mg/mL of diethyltoluamide in carbon disulfide prepared as follows. Transfer a quantity of Topical Solution, equivalent to 200 mg of diethyltoluamide, into a beaker. Place the beaker into a vacuum oven containing silica gel and calcium chloride, and adjusted to a pressure of about 380 mm of mercury, and heat at 35° for 6 h. Transfer the residue with the aid of carbon disulfide to a 10-mL volumetric flask, and add carbon disulfide to volume.

Analysis: Spectral region between 8 and 15 µm

Acceptance criteria: Meets the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: 1 mL of phosphoric acid in 1000 mL of water

Mobile phase: Methanol and *Solution A* (45:55)

Diluent: Methanol and water (45:55)

System suitability solution: 0.2 mg/mL of USP Diethyltoluamide RS (*m*-isomer) and 0.02 mg/mL of USP Diethyltoluamide Related Compound A RS in *Diluent*. [Note—USP Diethyltoluamide Related Compound A RS is the *p*-isomer of diethyltoluamide.]

Standard solution: 0.2 mg/mL of USP Diethyltoluamide RS in *Diluent*

Sample solution: Nominally 0.2 mg/mL of diethyltoluamide in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between diethyltoluamide (*m*-isomer) and diethyltoluamide (*p*-isomer), *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of the *m*-isomer of diethyltoluamide ($C_{12}H_{17}NO$) in the portion of Topical Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration in the *Standard solution* (mg/mL)

C_U = nominal concentration in the *Sample solution* (mg/mL)

Acceptance criteria: 92.0%–108.0%

OTHER COMPONENTS

• **Alcohol Determination** ⟨611⟩*(if present)*: 29.0%–89.0% of alcohol (C_2H_5OH) is found.

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Diethyltoluamide RS

USP Diethyltoluamide Related Compound A RS

N,N-Diethyl-4-toluamide.

$C_{12}H_{17}NO$ 191.27

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DIETHYLTOLUAMIDE TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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