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Dimethyl Sulfoxide Topical Solution

» Dimethyl Sulfoxide Topical Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled concentration of C_2H_6OS.

Packaging and storage—Preserve in tight, light-resistant containers.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—
USP Dimethyl Sulfoxide RS

Identification—

A: The chromatogram of the *Assay preparation*, obtained as directed in the *Assay*, exhibits a major peak for dimethyl sulfoxide, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation*, obtained as directed in the *Assay*.

B: To 2 mL of Topical Solution in a test tube add 5 mL of cold hydriodic acid. Filter the mixture rapidly, and collect the precipitate. Dry the precipitate in vacuum: a deep violet, crystalline solid is obtained, and it is soluble in chloroform, yielding a red solution.

Change to read:

C: To 0.1 g of solid sodium hydroxide in a test tube add 10 mL of Topical Solution, and heat on a steam bath until the sodium hydroxide has dissolved. Add 10 mL of chloroform, and shake. Filter the chloroform layer through a filter funnel containing about 10 g of anhydrous sodium sulfate. Heat the filtrate on a steam bath to remove the chloroform. Determine the IR spectrum of the liquid residue as directed under ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197F*▲ (CN 1-May-2020). The spectrum so obtained corresponds to that of a spectrum of USP Dimethyl Sulfoxide RS, similarly prepared.

Assay—[Note—Use glass equipment to prepare solutions.]

Internal standard solution—Transfer 3.0 mL of dimethylformamide to a 250-mL volumetric flask. Add about 200 mL of acetone, and shake for about 1 minute. Dilute with acetone to volume, and mix.

Standard preparation—Transfer about 2 g of USP Dimethyl Sulfoxide RS, accurately weighed, to a 250-mL volumetric flask, add 3.0 mL of dimethylformamide and 200 mL of acetone, and sonicate for about 1 minute. Dilute with acetone to volume, and mix to obtain a solution having a known concentration of about 8 mg of USP Dimethyl Sulfoxide RS per mL.

Assay preparation—Transfer an accurately measured volume of Topical Solution, equivalent to about 2 g of dimethyl sulfoxide, to a 250-mL volumetric flask, add 3.0 mL of dimethylformamide and about 200 mL of acetone, and sonicate for about 1 minute. Dilute with acetone to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The gas chromatograph is equipped with a flame-ionization detector and a 4-mm × 1.8-m column packed with 10% liquid phase G16 on support S1A. The column is maintained at about 170°, the injection port at about 200°, and the detector block at about 300°. The carrier gas is helium, flowing at a rate of about 20 mL per minute. Chromatograph two portions of the acetone used to prepare the *Standard preparation*, the *Assay preparation*, and the *Internal standard solution*, and record the peak responses as directed under *Procedure*. Discard the first chromatogram, and examine the second to confirm that there are no peaks present that would interfere with the measurement of the dimethylformamide peaks and the dimethyl sulfoxide peaks in subsequent chromatograms. Chromatograph the *Internal standard solution*, and record the peak responses as directed for *Procedure:* examine the chromatogram to confirm that there are no peaks present that would interfere with the measurement of the dimethylformamide peaks and the dimethyl sulfoxide peaks in subsequent chromatograms. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.2 for acetone, 0.5 for dimethylformamide, and 1.0 for dimethyl sulfoxide; the resolution, *R,* between the dimethylformamide peak and the dimethyl sulfoxide peak is not less than 2; the tailing factors for the dimethylformamide peak and the dimethyl sulfoxide peak are not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—[Note—Use peak heights where peak responses are indicated.] Separately inject equal volumes (about 2 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms for not less than 20 minutes, and measure the responses for the dimethylformamide and dimethyl sulfoxide peaks. Calculate the percentage (v/v) of C_2H_6OS in the portion of Topical Solution taken by the formula:

$$(2.5/1.096)10(C/V)(R_U/R_S)$$

in which 1.096 is the specific gravity of dimethyl sulfoxide, C is the concentration, in mg per mL, of USP Dimethyl Sulfoxide RS in the *Standard preparation;* V is the volume, in mL, of Topical Solution taken to prepare the *Assay preparation;* and R_U and R_S are the ratios of the dimethyl sulfoxide peak response to the dimethylformamide peak response in the chromatograms obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
DIMETHYL SULFOXIDE TOPICAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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