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Dimethyl Sulfoxide Irrigation

DEFINITION

Dimethyl Sulfoxide Irrigation is a sterile solution of Dimethyl Sulfoxide in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of dimethyl sulfoxide (C_2H_6OS).

IDENTIFICATION

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

ASSAY

Change to read:

• **Procedure**

▲**Diluent:** 1 mg/mL of ethyl benzoate in methanol

Standard solution: 1 mg/mL of USP Dimethyl Sulfoxide RS in *Diluent*

Sample solution: Nominally equivalent to 1 mg/mL of dimethyl sulfoxide from Dimethyl Sulfoxide Irrigation in *Diluent*

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary column coated with a 3-µm film of phase G43

Temperatures

Injection port: 250°

Detector: 250°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	0	100	2
100	10	200	3

Carrier gas: Hydrogen

Flow rate: 5 mL/min

Injection volume: 1 µL

Injection type: Split, split ratio 5:1

System suitability

Sample: *Standard solution*

[Note—The relative retention times for dimethyl sulfoxide and ethyl benzoate are 1.0 and 1.8, respectively.]

Suitability requirements

Tailing factor: NMT 1.5 for dimethyl sulfoxide

Relative standard deviation: NMT 0.5% for the peak response ratio of dimethyl sulfoxide to ethyl benzoate

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dimethyl sulfoxide (C_2H_6OS) in the portion of Dimethyl Sulfoxide Irrigation taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of dimethyl sulfoxide to ethyl benzoate from the *Sample solution*

R_S = peak response ratio of dimethyl sulfoxide to ethyl benzoate from the *Standard solution*

C_S = concentration of USP Dimethyl Sulfoxide RS in the *Standard solution* (mg/mL)

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

▲ (USP 1-Dec-2024)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: Nominally equivalent to 50 mg/mL of dimethyl sulfoxide from Irrigation in water

Acceptance criteria: 5.0–7.0

• **Sterility Tests** ⟨71⟩**:** Meets the requirements

Change to read:

• **Bacterial Endotoxins Test** ⟨85⟩**:** ▲Meets the requirements▲ (USP 1-Dec-2024)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose containers. Store at controlled room temperature, protected from strong light.

• **Labeling:** Label it to indicate prominently that it is not intended for injection.

• **USP Reference Standards** ⟨11⟩

USP Dimethyl Sulfoxide RS

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

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

Chromatographic Database Information: Chromatographic Database

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