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Deferoxamine Mesylate for Injection

DEFINITION

Deferoxamine Mesylate for Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of deferoxamine mesylate ($C_{25}H_{48}N_6O_8 \cdot CH_4O_3S$).

IDENTIFICATION

• **A.**

Sample: 5 mg of Deferoxamine Mesylate for Injection

Analysis: Dissolve the *Sample* in 5 mL of water, add 2 mL of tribasic sodium phosphate solution (1 in 200), mix, then add 10 drops of β-naphthoquinone-4-sodium sulfonate solution (1 in 40).

Acceptance criteria: A blackish brown color is produced.

ASSAY

• **Procedure**

Solution A: Dissolve 6.7 g of ferric chloride in dilute hydrochloric acid (1 in 100) in a 100-mL volumetric flask. Add dilute hydrochloric acid (1 in 100) to volume.

Standard solution: 1 mg/mL of USP Deferoxamine Mesylate RS

Sample solution: Nominally 1 mg/mL, pepared as follows. Constitute the contents of 1 vial in water, and dilute with water to volume.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: Vis

Analytical wavelength: 485 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Pipet 2 mL each of the *Standard solution*, *Sample solution*, and *Blank* into separate 25-mL volumetric flasks. To each flask add 3 mL of *Solution A*, and dilute with water to volume. Concomitantly determine the absorbances.

Calculate the percentage of the labeled amount of deferoxamine mesylate ($C_{25}H_{48}N_6O_8 \cdot CH_4O_3S$) in the portion of Deferoxamine Mesylate for Injection taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units** ⟨905⟩**:** Meets the requirements

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–6.0, in a solution (1 in 100)

• **Water Determination, *Method I*⟨921⟩:** NMT 1.5%

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

• **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 0.33 USP Endotoxin Unit/mg of deferoxamine mesylate

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩, *Specific Tests, Completeness and clarity of solutions*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

• **USP Reference Standards** ⟨11⟩

USP Deferoxamine Mesylate RS

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

Topic/Question	Contact	Expert Committee
DEFEROXAMINE MESYLATE FOR INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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