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Change to read:

Manganese Sulfate Injection

▲▲ (USP 1-May-2023)

DEFINITION

Manganese Sulfate Injection is a sterile solution of Manganese Sulfate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of manganese (Mn).

IDENTIFICATION

• **A.** The *Sample solution*, prepared as directed in the *Assay*, exhibits an absorption maximum at about 279 nm when tested as directed for in the *Assay*.

ASSAY

• **Procedure**

Solution A: 0.9 mg/mL of sodium chloride

Standard stock solution A: 1 mg/mL of manganese prepared as follows. Transfer 1.000 g of manganese to a 1000-mL volumetric flask, dissolve in 20 mL of nitric acid, and dilute with 0.1 N hydrochloric acid to volume. Store in a polyethylene bottle.

Standard stock solution B: 20 µg/mL of manganese from *Standard stock solution A* in water

Standard solution A: 1.6 µg/mL of manganese prepared as follows. Transfer 4.0 mL of *Standard stock solution B* to a 50-mL volumetric flask containing 10 mL of *Solution A*, and dilute with water to volume.

Standard solution B: 2.0 µg/mL of manganese prepared as follows. Transfer 5.0 mL of *Standard stock solution B* to a 50-mL volumetric flask containing 10 mL of *Solution A*, and dilute with water to volume.

Standard solution C: 2.4 µg/mL of manganese prepared as follows. Transfer 6.0 mL of *Standard stock solution B* to a 50-mL volumetric flask containing 10 mL of *Solution A*, and dilute with water to volume.

Sample solution: Nominally 0.002 mg/mL of manganese from a volume of Injection in water

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometer

Analytical wavelength: Manganese emission line at 279 nm

Source: Manganese hollow-cathode lamp

Flame: Air–acetylene

Blank: 0.18 mg/mL of sodium chloride

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, *Sample solution*, and *Blank*

Plot the absorbances of the *Standard solutions* versus concentration, in µg/mL, of manganese, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, C_S, in µg/mL, of manganese in the *Sample solution*.

Calculate the percentage of the labeled amount of manganese in the portion of Injection taken:

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

C_S = concentration of manganese in the *Sample solution*, determined from the calibration graph (µg/mL)

C_U = nominal concentration of manganese in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

Change to read:

• **Bacterial Endotoxins Test** ⟨85⟩**:** ▲Meets the requirements▲ (USP 1-May-2023)

• **pH** ⟨791⟩**:** 2.0–3.5

• **Particulate Matter in Injections** ⟨788⟩**:** It meets the requirements for small-volume injections.

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

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Label the Injection to indicate that it is to be diluted to the appropriate strength with Sterile Water for Injection or other suitable fluid prior to administration.

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

Topic/Question	Contact	Expert Committee
MANGANESE SULFATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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