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Magnesium Sulfate in Dextrose Injection

DEFINITION

Magnesium Sulfate in Dextrose Injection is a sterile solution of Magnesium Sulfate and Dextrose in Water for Injection. It contains NLT 93.0% and NMT 107.0% of the labeled amount of magnesium sulfate ($MgSO_4 \cdot 7H_2O$) and NLT 90.0% and NMT 110.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$).

IDENTIFICATION

• **A.**

Sample solution 1: A suitable volume of Injection equivalent to 50 mg/mL of dextrose

Analysis 1: Add a few drops of the *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.

Acceptance criteria 1: A copious red precipitate of cuprous oxide is formed.

Analysis 2: Proceed as directed in *Identification Tests—General* ⟨191⟩, *Magnesium*.

Acceptance criteria 2: Meets the requirements

ASSAY

• **Magnesium Sulfate**

Sample: A known volume of Injection equivalent to 250 mg of anhydrous magnesium sulfate

Titrimetric system

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a beaker, and dilute with water to 100 mL. Adjust with 1 N sodium hydroxide to a pH of 7 using pH indicator paper (see *Reagents, Indicators, and Solutions—Indicator and Test Papers*), and add 5 mL of ammonia-ammonium chloride buffer TS and 0.15 mL of eriochrome black TS. Titrate with *Titrant* to a blue endpoint. Each mL of *Titrant* is equivalent to 12.32 mg of magnesium sulfate ($MgSO_4 \cdot 7H_2O$).

Acceptance criteria: 93.0%–107.0% of the labeled amount of magnesium sulfate ($MgSO_4 \cdot 7H_2O$)

• **Dextrose**

Sample solution: Nominally 2 g/100 mL of dextrose prepared as follows. Transfer a suitable volume of Injection to a 100-mL volumetric flask. Add 0.2 mL of 6 N ammonium hydroxide, and dilute with water to volume.

Analysis: Determine the angular rotation in a suitable polarimeter tube (see *Optical Rotation* ⟨781⟩).

Calculate the percentage of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken:

$$\text{Result} = [(100 \times a)/(l \times \alpha)] \times (1/C_U) \times (M_{r1}/M_{r2}) \times 100$$

a = observed angular rotation of the *Sample solution* (°)

l = length of the polarimeter tube, decimeter

α = midpoint of the specific rotation range for anhydrous dextrose, 52.9°

C_U = nominal concentration of dextrose in the *Sample solution*, g/100 mL

M_{r1} = molecular weight of dextrose monohydrate, 198.17

M_{r2} = molecular weight of anhydrous dextrose, 180.16

Acceptance criteria: 90.0%–110.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$)

IMPURITIES

• **Limit of 5-Hydroxymethylfurfural and Related Substances**

Sample solution: Nominally 2 mg/mL of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in water from a suitable volume of Injection containing 1.0 g of dextrose in water

Instrumental conditions

Mode: UV

Analytical wavelength: 284 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Sample solution* and *Blank*

Acceptance criteria: Absorbance of the *Sample solution* is NMT 0.25.

SPECIFIC TESTS

• **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 0.039 USP Endotoxin Unit/mg of magnesium sulfate

• **pH** ⟨791⟩**:** 3.5–6.5

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type 1 or Type II glass.

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

Topic/Question	Contact	Expert Committee
MAGNESIUM SULFATE IN DEXTROSE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

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