

Magnesium Sulfate Injection

DEFINITION
Magnesium Sulfate Injection is a sterile solution of Magnesium Sulfate in Water for Injection. It contains magnesium sulfate (MgSO_4) equivalent to NLT 93.0% and NMT 107.0% of the labeled amount of magnesium sulfate heptahydrate ($\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$).

IDENTIFICATION
• **A. IDENTIFICATION TESTS—GENERAL, [Magnesium\(191\)](#) and [Sulfate\(191\)](#):** Meets the requirements

ASSAY
• **PROCEDURE**
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
Sample: *Sample*
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—Indicators and Indicator Test Papers](#)). 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* consumed is equivalent to 12.32 mg of magnesium sulfate heptahydrate ($\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$).
Acceptance criteria: 93.0%–107.0%

SPECIFIC TESTS
• **[BACTERIAL ENDOTOXINS TEST \(85\)](#):** It contains NMT 0.09 USP Endotoxin Unit/mg of magnesium sulfate.
• **[pH \(791\)](#):**
Sample solution: 50 mg/mL
Acceptance criteria: 5.5–7.0
• **[PARTICULATE MATTER IN INJECTIONS \(788\)](#):** Meets the requirements for small-volume injections
• **OTHER REQUIREMENTS:** It meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS
• **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass.
• **LABELING:** The label states the total osmolar concentration in mOsmol/L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol/mL.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

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