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Zinc Sulfate Injection

DEFINITION

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

IDENTIFICATION

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

ASSAY

• PROCEDURE

[NOTE—The *Standard solutions* and the *Sample solution* may be diluted quantitatively with water, if necessary, to obtain solutions of suitable concentrations adaptable to the linear or working range of the instrument.]

Sodium chloride solution: 0.9 mg/mL of sodium chloride in water

Standard stock solution A: 10 mg/mL of zinc in water prepared as follows. Transfer 3.11 g of zinc oxide to a 250-mL volumetric flask. Add 80 mL of 1 N sulfuric acid, warm to dissolve, and cool. Dilute with water to volume.

Standard stock solution B: 125 µg/mL of zinc in water, from *Standard stock solution A*

Standard solution A: Transfer 2.0 mL of the *Standard stock solution B* and 5 mL of *Sodium chloride solution* into a 500-mL volumetric flask, and dilute with water (0.50 µg/mL of zinc).

Standard solution B: Transfer 3.0 mL of the *Standard stock solution B* and 5 mL of *Sodium chloride solution* into a 500-mL volumetric flask, and dilute with water (0.75 µg/mL of zinc).

Standard solution C: Transfer 4.0 mL of the *Standard stock solution B* and 5 mL of *Sodium chloride solution* into a 500-mL volumetric flask, and dilute with water (1.0 µg/mL of zinc).

Sample solution: Transfer a volume of Injection, equivalent to 5 mg of zinc, to a 500-mL volumetric flask. Dilute with water to volume.

Transfer 10.0 mL of this solution to a 100-mL volumetric flask. From the labeled amount of sodium chloride, if any, in the Injection, calculate the amount, in mg, of sodium chloride in the 10.0-mL portion and add sufficient *Sodium chloride solution* to bring the total sodium chloride content of the 100-mL volumetric flask to 0.9 mg. Dilute with water to volume.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Zinc emission line at 213.8 nm

Lamp: Zinc hollow-cathode

Flame: Air–acetylene

Blank: Water

Analysis

Samples: *Standard solutions* and *Sample solution*

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

Calculate the percentage of zinc (Zn) in the Injection:

$$\text{Result} = (C_o/C_u) \times 100$$

C_o = concentration of zinc in the *Sample solution* as determined from the standard curve (observed concentration, µg/mL)

C_u = nominal concentration of the *Sample solution*, based on the label claim of the Injection and the dilution factor (calculated concentration, µg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

- **PARTICULATE MATTER IN INJECTIONS (788)**: Meets the requirements for small-volume injections

SPECIFIC TESTS

- **BACTERIAL ENDOTOXINS TEST (85)**: It contains NMT 25.0 USP Endotoxin Units/mg of zinc.
- **pH (791)**: 2.0–4.0
- **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.
- **LABELING**: Label the Injection in terms of its content of anhydrous zinc sulfate ($ZnSO_4$) and in terms of its content of elemental zinc. Label it to state that it is not intended for direct injection but is to be added to other intravenous solutions.

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

Topic/Question	Contact	Expert Committee
ZINC SULFATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

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