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**Add the following:**

## ^Zinc Sulfate Compounded Injection

### DEFINITION

Zinc Sulfate Compounded Injection contains NLT 90.0% and NMT 110.0% of the labeled content of zinc (Zn). Prepare Zinc Sulfate Compounded Injection containing 1 mg/mL or 5 mg/mL of zinc as follows (see [Pharmaceutical Compounding—Sterile Preparations \(797\)](#)).

#### For Zinc Sulfate Compounded Injection containing 1-mg/mL

Zinc	100 mg (274 mg as zinc sulfate monohydrate; or 440 mg as zinc sulfate heptahydrate)
Sulfuric Acid or Sodium Hydroxide	To adjust pH to 2.0–4.0
Sterile Water for Injection, a sufficient quantity to make	100 mL

#### For Zinc Sulfate Compounded Injection containing 5-mg/mL

Zinc	500 mg (1372 mg as zinc sulfate monohydrate; or 2199 mg as zinc sulfate heptahydrate)
Sulfuric Acid or Sodium Hydroxide	To adjust pH to 2.0–4.0
Sterile Water for Injection, a sufficient quantity to make	100 mL

Dissolve the *Zinc Sulfate Monohydrate* or the *Zinc Sulfate Heptahydrate* in 95 mL of *Sterile Water for Injection*. Adjust with *Sulfuric Acid* or *Sodium Hydroxide* to a pH between 2.0 and 4.0. Add sufficient *Sterile Water for Injection* to bring to final volume, and mix well. Pass through a compatible filter of 1.2- $\mu$ m pore size to remove particulate matter and sterilize by autoclave.

### ASSAY

#### • PROCEDURE

**Mobile phase:** 3 mM nitric acid

**Standard solution:** 0.01 mg/mL of zinc prepared from [USP Zinc Sulfate RS](#) and water

**Sample solution:** For a 1-mg/mL Injection, transfer 1.0 mL of the compounded preparation to a 100-mL volumetric flask, dilute with water to volume, and mix well. For a 5-mg/mL Injection, transfer 0.2 mL of the compounded preparation to a 100-mL volumetric flask, dilute with water to volume, and mix well.

#### Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

**Mode:** LC

**Detector:** Conductivity

**Column:** 4.0-mm  $\times$  10-cm; packing [L76](#)

**Column temperature:** 40°

**Flow rate:** 0.9 mL/min

**Injection volume:** 10  $\mu$ L

#### System suitability

**Sample:** *Standard solution*

[NOTE—The retention time for zinc is about 7.0 min.]

#### Suitability requirements

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0% for replicate injections

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of zinc (Zn) in the portion of Injection taken:

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

$r_U$  = peak response of zinc from the *Sample solution*

$r_S$  = peak response of zinc from the *Standard solution*

$C_S$  = concentration of zinc from [USP Zinc Sulfate RS](#) in the *Standard solution* (mg/mL)

$C_U$  = nominal concentration of zinc in the *Sample solution* (mg/mL)

**Acceptance criteria:** 90.0%–110.0%

#### SPECIFIC TESTS

- **pH (791):** 2.0–4.0
- **STERILITY TESTS (71), *Test for Sterility of the Product to Be Examined, Membrane Filtration*:** Meets the requirements
- **BACTERIAL ENDOTOXINS TEST (85):** NMT 25.0 USP Endotoxin Units/mg of zinc
- **PARTICULATE MATTER IN INJECTIONS (788):** Meets the requirements

#### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in single-dose sterile containers, preferably of Type I or Type II glass, and store at controlled room temperature.
- **BEYOND-USE DATE:** In the absence of performing and completing a sterility and endotoxins test, the *Beyond-Use Dates* in [Pharmaceutical Compounding—Sterile Preparations \(797\)](#) apply. After successful completion of sterility and endotoxins testing, NMT 90 days after the date on which it was compounded when stored at controlled room temperature.
- **LABELING:** Label it to indicate that it is for use in a single patient only, and to state the *Beyond-Use Date*. Label the Injection in terms of its content of anhydrous zinc sulfate ( $\text{ZnSO}_4$ ) 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.
- **USP REFERENCE STANDARDS (11):**  
[USP Zinc Sulfate RS](#) ▲ (USP 1-Aug-2020)

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

Topic/Question	Contact	Expert Committee
ZINC SULFATE COMPOUNDED INJECTION	<a href="#">Brian Serumaga</a> Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	CMP2020 Compounding 2020

**Chromatographic Database Information:** [Chromatographic Database](#)

#### Most Recently Appeared In:

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