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## Zinc Sulfate Ophthalmic Solution

### DEFINITION

Zinc Sulfate Ophthalmic Solution is a sterile solution of Zinc Sulfate in Water rendered isotonic by the addition of suitable salts. It contains NLT 95.0% and NMT 105.0% of the labeled amount of zinc sulfate ( $\text{ZnSO}_4$ ).

### IDENTIFICATION

- **A.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Sulfate](#): Meets the requirements
- **B.** The retention time of the zinc peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

### ASSAY

**Change to read:**

#### • PROCEDURE

Proceed as directed in [▲Zinc Determination \(591\), Ion Chromatographic Method▲](#) (CN 1-May-2020) .

**Diluent:** 0.2% (w/v) [hydrochloric acid](#)

**Standard stock solution:** Prepare as directed in the chapter.

**Standard solution:** 20 µg/mL of [USP Zinc Oxide RS](#) in *Diluent* from the *Standard stock solution*

**Sample solution:** Nominally 40 µg/mL of zinc sulfate from a suitable volume of Ophthalmic Solution in *Diluent*

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0%

#### Analysis

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

Calculate the percentage of the labeled amount of zinc sulfate ( $\text{ZnSO}_4$ ) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

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

$C_S$  = concentration of [USP Zinc Oxide RS](#) in the *Standard solution* (µg/mL)

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

$M_{r1}$  = molecular weight of zinc sulfate, 161.44

$M_{r2}$  = molecular weight of zinc oxide, 81.38

**Acceptance criteria:** 95.0%–105.0%

### SPECIFIC TESTS

- [STERILITY TESTS \(71\)](#): Meets the requirements
- [pH \(791\)](#): 5.8–6.2, or if it contains sodium citrate, 7.2–7.8
- **OTHER REQUIREMENTS:** It meets the requirements in [Ophthalmic Products—Quality Tests \(771\)](#).

### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

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

| Topic/Question                   | Contact                                                                     | Expert Committee          |
|----------------------------------|-----------------------------------------------------------------------------|---------------------------|
| ZINC SULFATE OPHTHALMIC SOLUTION | <a href="#">Documentary Standards Support</a>                               | SM32020 Small Molecules 3 |
| REFERENCE STANDARD SUPPORT       | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | SM32020 Small Molecules 3 |

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

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