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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 (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 $\mu\text{g}/\text{mL}$ of [USP Zinc Oxide RS](#) in *Diluent* from the *Standard stock solution*

Sample solution: Nominally 40 $\mu\text{g}/\text{mL}$ 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 (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* ($\mu\text{g}/\text{mL}$)

C_U = nominal concentration of zinc sulfate in the *Sample solution* ($\mu\text{g}/\text{mL}$)

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	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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