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Zinc Sulfate Oral Solution

DEFINITION

Zinc Sulfate Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of zinc sulfate monohydrate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$). It may contain one or more suitable flavors and sweeteners.

IDENTIFICATION

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

ASSAY

PROCEDURE

Sample: An accurately measured volume of Oral Solution, equivalent to 99 mg of zinc sulfate monohydrate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$)

Blank: 60 mL of water and 10 mL of ammonia–ammonium chloride buffer TS. Add 0.1 mL of eriochrome black TS.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 250-mL flask. Add 50 mL of water and 10 mL of ammonia–ammonium chloride buffer TS and 0.3 mL of eriochrome black TS. Titrate with *Titrant* to a green endpoint.

Calculate the percentage of the labeled amount of zinc sulfate monohydrate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$) in the portion of Oral Solution taken:

$$\text{Result} = \left\{ \left[(V_s - V_b) \times M \times F \right] / W \right\} \times 100$$

V_s = *Titrant* volume consumed by the *Sample* (mL)

V_b = *Titrant* volume consumed by the *Blank* (mL)

M = actual molarity of the *Titrant* (mM/mL)

F = equivalency factor, 179.46 mg/mM

W = nominal amount of zinc sulfate monohydrate in the *Sample* (mg)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **SPECIFIC GRAVITY (841):** 1.18–1.24
- **pH (791):** 2.5–4.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store in a cool, dry place protected from light.
- **LABELING:** Label the Oral Solution in terms of zinc sulfate monohydrate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$) and in terms of elemental zinc.

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

Topic/Question	Contact	Expert Committee
ZINC SULFATE ORAL SOLUTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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