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Zinc Acetate Oral Solution

DEFINITION

Zinc Acetate Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of zinc (Zn) as zinc acetate dihydrate ($C_4H_6O_4Zn \cdot 2H_2O$). It may contain one or more suitable flavors and sweeteners, which are recognized as safe, in amounts that are unobjectionable.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, Zinc (191) and Acetate (191):** Meets the requirements

ASSAY

• PROCEDURE

Sample: An accurately measured volume of Oral Solution, equivalent to 40 mg of zinc

Blank: 100 mL of water, 5 mL of ammonia–ammonium chloride buffer TS, and 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 100 mL of water, 5 mL of ammonia–ammonium chloride buffer TS, and 0.1 mL of eriochrome black TS. Titrate with *Titrant* to a green endpoint.

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

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

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

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

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

F = equivalency factor, 65.4 mg/mmol

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH (791):** 5.7–6.3
- **MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62):** The total aerobic microbial count does not exceed 10^2 cfu/mL. The total molds and yeasts count does not exceed 10^1 cfu/mL. It meets the requirement of the test for absence of *Escherichia coli*.

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 acetate dihydrate ($C_4H_6O_4Zn \cdot 2H_2O$) 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 ACETATE 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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