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Zinc Sulfate Tablets

DEFINITION

Zinc Sulfate Tablets contain NLT 95.0% and NMT 105.0% 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

• A. SULFATE

Sample solution: Dissolve a portion of powdered Tablets, nominally equivalent to 5 g of zinc sulfate, in 100 mL of water, filter in a Buchner funnel under vacuum, and use the filtrate.

Hydrochloric acid solution: Dilute 20 g of hydrochloric acid with water to 100 mL.

Barium chloride solution: 61 mg/mL of barium chloride

Analysis: To 5 mL of the *Sample solution* add 1 mL of *Hydrochloric acid solution* and 1 mL of *Barium chloride solution*.

Acceptance criteria: A white precipitate is formed.

• B. ZINC

Sample solution: Proceed as directed in *Identification test A*.

Sodium hydroxide solution: 420 mg/mL of sodium hydroxide

Ammonium chloride solution: 107 mg/mL of ammonium chloride

Glycerin solution: A mixture of glycerin and water (85:15)

Sodium sulfide solution: Dissolve 12 g of sodium sulfide with heating in a 45-mL mixture of *Glycerin solution* and water (29:10). Allow to cool, and dilute with the same mixture of solvents to 100 mL. The solution should be colorless.

Analysis: To 5 mL of the *Sample solution* add 0.2 mL of *Sodium hydroxide solution*.

Acceptance criteria: A white precipitate is formed. When an additional 2 mL of *Sodium hydroxide solution* is added, the precipitate dissolves. When 10 mL of *Ammonium chloride solution* is added, the solution remains clear. When 0.1 mL of *Sodium sulfide solution* is added, a white precipitate is formed.

ASSAY

• PROCEDURE

Sample: Portion of the powder, equivalent to 90 mg of zinc (about 247 mg of zinc sulfate monohydrate), from NLT 20 finely powdered Tablets

Blank: Proceed as directed in the *Analysis*, but without the *Sample*.

Titrimetric system

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

Mode: Direct titration

Titrant: 0.1 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a suitable flask or beaker. Dissolve in 15 mL of dilute acetic acid, and sonicate for 15 min. Add 200 mL of water and 50 mg of xylene orange triturate, and mix. [NOTE—For preparation of xylene orange triturate, triturate 1 part of xylene orange with 99 parts of potassium nitrate. Xylene orange triturate, 1% is also commercially available.¹] Neutralize the solution with 2 g of methenamine until the solution is a violet-pink color. Titrate with *Titrant* until the solution is yellow. [NOTE—Add the titrant slowly near the endpoint with expedited stirring.] Perform a *Blank* determination.

Calculate the percentage of the labeled amount of zinc sulfate monohydrate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$) in the *Sample* 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: 95.0%–105.0%

PERFORMANCE TESTS

- [DISINTEGRATION \(701\)](#)

Time: 60 s

Acceptance criteria: Meet the requirements

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at controlled room temperature.
- **LABELING:** Label the Tablets in terms of zinc sulfate monohydrate ($ZnSO_4 \cdot H_2O$) and in terms of elemental zinc.

¹ Ricca Chemical Company, part number 9395-100.

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

Topic/Question	Contact	Expert Committee
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