tions of *Dithizone Extraction Solution,* draining off each extract into another separator, until the last portion of dithizone solution retains its green color. Shake the combined extracts for 30 s with 20 mL of 0.2 N nitric acid, and discard the chloroform layer. Add to the acid solution 4.0 mL of *Ammonia–Cyanide Solution* and 2 drops of *Hydroxylamine Hydrochloride Solution*. Add 10.0 mL of *Standard Dithizone Solution*, and shake the mixture for 30 s. Pass the chloroform layer through an acid-washed filter paper into a color-comparison tube.

Acceptance criteria: The color of the *Test preparation* does not exceed that of the *Standard solution* (NMT 10 ppm).

- **ALKALIES AND ALKALINE EARTHS**

Sample solution: Mix 2.0 g with 50 mL of water, and add 10 mL of hydrochloric acid. Boil until the solution is clear, filter while hot, and wash the separated fatty acids with about 50 mL of hot water. Render the combined filtrate and washings alkaline with 6 N ammonium hydroxide. Add ammonium sulfide TS to precipitate the zinc completely, dilute with water to 200 mL, mix, and filter.

Analysis: To 100 mL of the clear filtrate add 0.5 mL of sulfuric acid, evaporate to dryness, and ignite to constant weight.

Acceptance criteria: The weight of the residue does not exceed 10 mg (1.0%).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Zinc Sulfate

$ZnSO_4 \cdot xH_2O$

Sulfuric acid, zinc salt (1:1), hydrate;

Zinc sulfate (1:1) monohydrate	179.46
Zinc sulfate (1:1) heptahydrate [7446-20-0].	287.56
Anhydrous [7733-02-0].	161.46

DEFINITION

Zinc Sulfate contains one or seven molecules of water of hydration. The monohydrate contains NLT 89.0% and NMT 90.4% of $ZnSO_4$, corresponding to NLT 99.0% and NMT 100.5% of $ZnSO_4 \cdot H_2O$, and the heptahydrate contains NLT 55.6% and NMT 61.0% of $ZnSO_4$, corresponding to NLT 99.0% and NMT 108.7% of $ZnSO_4 \cdot 7H_2O$.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL,** *Zinc* ⟨**191**⟩**:** Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL,** *Sulfate* ⟨**191**⟩**:** Meets the requirements

ASSAY

- **PROCEDURE**

Sample solution: Equivalent to 1.70 mg/mL of $ZnSO_4$ in water

Analysis: To 100 mL of the *Sample solution* add 5 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS until the solution is deep blue in color. Each mL of 0.05 M edetate disodium is equivalent to 8.072 mg of $ZnSO_4$.

Acceptance criteria

Monohydrate: 89.0%–90.4% of $ZnSO_4$, corresponding to 99.0%–100.5% of $ZnSO_4 \cdot H_2O$

Heptahydrate: 55.6%–61.0% of $ZnSO_4$, corresponding to 99.0%–108.7% of $ZnSO_4 \cdot 7H_2O$

IMPURITIES

- **LIMIT OF ARSENIC,** *Method I* ⟨**211**⟩

Test preparation: Dissolve a portion equivalent to 215 mg of $ZnSO_4$ in 35 mL of water.

Acceptance criteria: NMT 14 ppm

- **LIMIT OF LEAD** ⟨**251**⟩

Standard solution: Combine 5 mL of water, 0.50 mL of *Standard Lead Solution* (see *Heavy Metals* ⟨231⟩), and 10 mL of *Potassium Cyanide Solution* (1 in 10) in a color-comparison tube.

Test preparation: Dissolve an amount equivalent to 0.25 g of $ZnSO_4$ in 5 mL of water, and transfer the solution to a similar, matched color-comparison tube. Add 10 mL of *Potassium Cyanide Solution* (1 in 10) and allow the mixture to become clear.

Analysis: To the *Standard solution* and the *Test preparation* add 0.1 mL of sodium sulfide TS. Mix the contents of each tube, and allow to stand for 5 min.

Acceptance criteria: Viewed downward over a white surface, the *Test preparation* is not darker than the *Standard solution* (NMT 20 ppm of lead).

- **ALKALIES AND ALKALINE EARTHS**

Sample solution: Dissolve the equivalent of 1.12 g of $ZnSO_4$ in 150 mL of water contained in a 200-mL volumetric flask. Add sufficient ammonium sulfide TS to precipitate the zinc completely, and dilute with water to volume. Pass through a dry filter, and reject the first portion of the filtrate.

Analysis: To 100 mL of the *Sample solution* filtrate add a few drops of sulfuric acid, evaporate to dryness in a tared dish, and ignite.

Acceptance criteria: The weight of the residue is NMT 5 mg (0.9%).

SPECIFIC TESTS

- **ACIDITY**

Sample solution: 28 mg/mL of $ZnSO_4$

Acceptance criteria: The *Sample solution* is not colored pink by methyl orange TS.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** The label indicates whether it is the monohydrate or the heptahydrate. Label any oral or parenteral preparations containing Zinc Sulfate to state the content of elemental zinc.

Zinc Sulfate Injection

» Zinc Sulfate Injection is a sterile solution of Zinc Sulfate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of zinc (Zn).

Packaging and storage—Preserve in single-dose or multiple-dose containers.

Labeling—Label the Injection in terms of its content of anhydrous zinc sulfate ($ZnSO_4$) and in terms of its content of elemental zinc. Label it to state that it is not intended for direct injection but is to be added to other intravenous solutions.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS

Identification—It responds to the tests for *Zinc* ⟨191⟩ and for *Sulfate* ⟨191⟩.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 25.0 USP Endotoxin Units per mg of zinc.

pH ⟨791⟩: between 2.0 and 4.0.

Particulate matter ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—[NOTE—The *Standard preparations* and the *Assay preparation* may be diluted quantitatively with water, if necessary, to