provide sufficient specificity, sensitivity, linearity, accuracy, and precision.]

System suitability

[NOTE—Analyze the *System suitability solution,* and obtain the response as directed for *Analysis*.]

Suitability requirements

Relative standard deviation: NMT 2.0%.

Analysis

Samples: *Standard solutions* and *Sample solution*

Determine the emission of each mineral of interest in the *Standard solutions* and *Sample solution* with an inductively coupled plasma system using the *Diluent* as the blank. Plot the emission of the *Standard solutions* versus the concentration, in mg/L of the minerals of interest, and draw the straight line best fitting the plotted points. From the graph so obtained, determine the concentration, C, in mg/L, for each mineral of interest in the *Sample solution*.

Calculate the percentage of the labeled amount for each mineral:

$$\text{Result} = C \times (V/W) \times F \times (C_W/L) \times 100$$

C = measured concentration of the relevant element in the *Sample solution* (mg/L)
V = volume of the *Sample solution* (L)
W = sample weight (mg)
F = dilution factor of the *Sample solution*
C_W = average Tablet weight (mg)
L = labeled amount/Tablet (mg)

Acceptance criteria: 90.0%–125.0% of the labeled amount of calcium (Ca), copper (Cu), iron (Fe), magnesium (Mg), manganese (Mn), phosphorus (P), and zinc (Zn); and 90.0%–160.0% of the labeled amounts of boron (B), chromium (Cr), molybdenum (Mo), nickel (Ni), selenium (Se), tin (Sn), and vanadium (V).

PERFORMANCE TESTS

- **DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS ⟨2040⟩:** Meet the requirements for *Dissolution*
- **WEIGHT VARIATION OF DIETARY SUPPLEMENTS ⟨2091⟩:** Meet the requirements

SPECIFIC TESTS

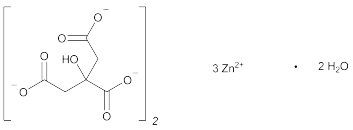
- **MICROBIAL ENUMERATION TESTS—NUTRITIONAL AND DIETARY SUPPLEMENTS ⟨2021⟩:** The total aerobic microbial count does not exceed 3000 cfu/g, and the combined molds and yeasts count does not exceed 300 cfu/g.
- **ABSENCE OF SPECIFIED MICROORGANISIMS—NUTRITIONAL AND DIETARY SUPPLEMENTS ⟨2022⟩:** Meet the requirements of the tests for absence of *Salmonella* species, *Escherichia coli*, and *Staphylococcus aureus*

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **LABELING:** The label states that the product is Water-Soluble Vitamins with Minerals Tablets. The label also states the quantity of each vitamin and mineral in terms of metric units per dosage unit and, where necessary, the chemical form in which a vitamin is present, and also states the salt form of the mineral used as the source of each element. Where more than one assay method is given for a particular vitamin, the labeling states which assay method is used only if *Method 1* is not used.

- **USP REFERENCE STANDARDS ⟨11⟩**
  USP Biotin RS
  USP Calcium Pantothenate RS
  USP Cyanocobalamin RS
  USP Folic Acid RS
  USP Niacin RS
  USP Niacinamide RS
  USP Pyridoxine Hydrochloride RS
  USP Riboflavin RS
  USP Sodium Fluoride RS
  USP Thiamine Hydrochloride RS

Zinc Citrate



$C_{12}H_{10}O_{14}Zn_3 \cdot 2H_2O$ 610.36

2-Hydroxy-1,2,3-propanetricarboxylic acid zinc salt, dihydrate [5990-32-9].
Anhydrous [546-46-3].

DEFINITION

Zinc Citrate contains NLT 31.3% of zinc (Zn), calculated on the dried basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL,** *Zinc* **⟨191⟩:** A solution (1 in 10) meets the requirements.
- **B. IDENTIFICATION TESTS—GENERAL,** *Citrate* **⟨191⟩:** A solution (1 in 10) meets the requirements.

ASSAY

- **PROCEDURE**

Sample: 350 mg of Zinc Citrate, previously dried at 105° for 2 h

Blank: 60 mL of water

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 60 mL of water. Add 10 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS. Titrate with the *Titrant* to a blue endpoint. Perform a blank determination.

Calculate the percentage of zinc (Zn) in the portion of Zinc Citrate taken:

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

V = sample titrant volume (mL)
B = blank titrant volume (mL)
M = titrant molarity (mM/mL)
F = equivalency factor, 65.4 mg/mM
W = sample weight (mg)

Acceptance criteria: NLT 31.3% on the dried basis

IMPURITIES

- **CHLORIDE AND SULFATE,** *Chloride* **⟨221⟩:** A 1.0-g portion shows no more chloride than corresponds to 0.7 mL of 0.020 N hydrochloric acid (NMT 0.05%).
- **CHLORIDE AND SULFATE,** *Sulfate* **⟨221⟩:** A 1.8-g portion shows no more sulfate than corresponds to 0.5 mL of 0.020 N sulfuric acid (NMT 0.05%).
- **LIMIT OF ARSENIC, CADMIUM, AND LEAD**

Arsenic standard solution: 1.0 µg/mL in 1% nitric acid, prepared from an arsenic standard solution (10 mg/L)

Cadmium standard solution: 1.0 µg/mL in 1% nitric acid, prepared from a cadmium standard solution (10 mg/L)
Lead standard solution: 1.0 µg/mL in 1% nitric acid, prepared from a lead standard solution (10 mg/L)
Multi-element standard solution: 10 µg/L of lead, 5 µg/L of cadmium, and 3 µg/L of arsenic in 1% nitric acid, prepared from the *Lead standard solution*, *Cadmium standard solution*, and *Arsenic standard solution*, respectively
Sample solution: 2 mg/mL of Zinc Citrate in 1% nitric acid
Instrumental conditions
(See *Plasma Spectrochemistry* ⟨730⟩.)
Mode: ICP-MS
Radio frequency: 1350 Watts
Nebulizer flow rate: 0.9 L/min
[NOTE—The radio frequency and nebulizer flow rate settings may be developed and optimized based on the manufacturer's recommendation.]
Detection atomic masses: As, Cd, and Pb
Blank: 1% nitric acid solution
Analysis
Samples: *Multi-element standard solution*, *Sample solution*, and *Blank*
Determine the responses of the *Multi-element standard solution, Sample solution,* and *Blank* at the masses indicated above.
Calculate the content of each element, in µg/g, in the portion of Zinc Citrate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U)$$

r_U = peak response of the corresponding element from the *Sample solution*
r_S = peak response of the corresponding element from the *Multi-element standard solution*
C_S = concentration of the corresponding element in the *Multi-element standard solution* (µg/L)
C_U = concentration of Zinc Citrate in the *Sample solution* (g/L)

Acceptance criteria
Arsenic: NMT 3 µg/g
Cadmium: NMT 5 µg/g
Lead: NMT 10 µg/g

SPECIFIC TESTS

- **LOSS ON DRYING ⟨731⟩:** Dry a sample at 105° for 2 h: it loses NMT 1.0% of its weight.
- **MICROBIAL ENUMERATION TESTS ⟨2021⟩:** The total aerobic microbial count does not exceed 10^3 cfu/g. The total combined yeasts and molds count does not exceed 10^2 cfu/g.
- **MICROBIOLOGICAL PROCEDURES FOR ABSENCE OF SPECIFIED MICROORGANISMS ⟨2022⟩:** It meets the requirements of the test for absence of *Escherichia coli*.

ADDITIONAL REQUIREMENTS

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

Zinc Citrate Tablets

DEFINITION

Zinc Citrate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of zinc (Zn).

IDENTIFICATION

- **A.** The *Sample solution* for *Strength* produces line emissions or absorptions at the characteristic wavelengths for zinc.
- **B. IDENTIFICATION TESTS—GENERAL,** *Citrate* ⟨191⟩
Sample solution: Transfer a quantity of powdered Tablets, equivalent to about 15 mg of zinc, to a centrifuge tube. Add 2–5 mL of water, sonicate for 1 min, shake, and centrifuge.
Acceptance criteria: Meets the requirements

STRENGTH

- **CONTENT OF ZINC**
Method 1
[NOTE—A standard stock solution is commercially available at different zinc concentrations, which may be used for preparation of the *Standard stock solution*. Necessary volumetric adjustment can be made in the *Standard solution*. Concentrations of the *Standard solution* and the *Sample solution* may be modified to fit the linear or working range of the instrument.]
Standard stock solution: Dissolve 625 mg of zinc oxide, weighed, and previously ignited to constant weight, in 10 mL of nitric acid, and add water to make 500.0 mL. This solution contains 1000 mg/L of zinc.
Standard solution: To a 500-mL volumetric flask add 200 mL of water and 10 mL of nitric acid, and mix thoroughly. Pipette 10.0 mL of the *Standard stock solution* into the volumetric flask, and dilute with water to volume to obtain a solution having a known concentration of about 20 mg/L of zinc.
Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer weighed portion of the powdered Tablets, equivalent to about 0.1 g of zinc, to a 50-mL flask. Add 10 mL of nitric acid, and heat the solution on a hot plate to boil gently, during which process fuming evolves. Boil the solution for an additional 30 min with constant swirling, during which no fuming should be observed. Cool the solution to room temperature, quantitatively transfer all of the solution to a 500-mL volumetric flask, dilute with water to volume, and mix. Pipette 25.0 mL of this solution into a 250-mL volumetric flask, add 5 mL of nitric acid, dilute with water to volume, mix, and filter.
Inductively coupled plasma system
(See *Plasma Spectrochemistry* ⟨730⟩.)
Mode: Atomic emission spectroscopy
Analytical wavelength: 206.20 nm. [NOTE—The operating conditions may be developed and optimized based on the manufacturer's recommendation. A typical setting includes radio frequency (RF) power of about 1300 watts, argon torch flow of about 15 L/min, argon auxiliary flow of about 0.2 L/min, and a nebulizer flow rate of about 0.8 L/min.]
Blank: 2% nitric acid solution
Analysis
Samples: *Standard solutions*, *Sample solution*, and *Blank*
Calculate the percentage of the labeled amount of zinc (Zn) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = response from the *Sample solution*
r_S = response from the *Standard solution*
C_S = concentration of the *Standard solution* (mg/L)
C_U = nominal concentration of zinc in the *Sample solution* (mg/L)

Acceptance criteria: 90.0%–110.0%
Method 2
Standard stock solution A: 1000 µg/mL of zinc from zinc oxide in 5 M hydrochloric acid (3.89 mg/mL) and diluted with water to final volume. [NOTE—Dissolve in 5 M hydrochloric acid by warming, if necessary. Cool, and then dilute to final volume.]
Standard stock solution B: 50 µg/mL of zinc from *Standard stock solution A* diluted with 0.125 N hydrochloric acid