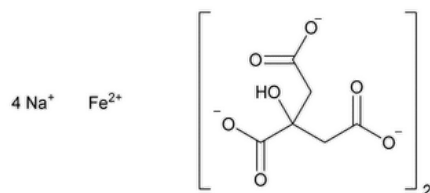


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Sodium Ferrous Citrate



$C_{12}H_{10}FeNa_4O_{14}$ 526.00

Tetrasodium biscitrato iron (II) CAS RN®: 43160-25-4.

DEFINITION

Sodium Ferrous Citrate contains NLT 10.0% and NMT 11.0% of iron (Fe), calculated on the as-is basis.

IDENTIFICATION

• A. SODIUM

Sample: Ignite 3 g of Sodium Ferrous Citrate at 500°–600° for 3 h.

Acceptance criteria: The residue obtained from the ignition imparts an intense yellow color to a nonluminous flame.

• B. IDENTIFICATION TESTS—GENERAL (191), [Chemical Identification Tests, Iron, A., Ferrous salts](#)

Sample solution: 10 mg/mL of Sodium Ferrous Citrate in 5% [hydrochloric acid](#)

Acceptance criteria: Meets the requirements

• C. CITRATE

Sample: 0.5 g of Sodium Ferrous Citrate

Analysis: Transfer the *Sample* to an appropriate container. Add 5 mL of water and 10 mL of 4% [potassium hydroxide](#) solution. Heat the solution in a water bath for 10 min while stirring well. Allow the solution to cool to room temperature and filter. Neutralize a portion of the filtrate with 50% [acetic acid](#), add an excessive amount of 7.5% [calcium chloride](#) solution, and boil. A white crystalline precipitate is formed. Collect the precipitate.

Acceptance criteria: The precipitate does not dissolve upon addition of 4% [sodium hydroxide](#) solution; the precipitate does dissolve in 25% [hydrochloric acid](#) solution.

• D. COMPLEX SALT OF FERROUS IRON AND CITRIC ACIDS

Sample solution: 10 mg/mL of Sodium Ferrous Citrate

Analysis: Add 2 mL of [stronger ammonia water](#) to 5 mL of the *Sample solution*.

Acceptance criteria: A red-brown color develops with no precipitation.

ASSAY

• CONTENT OF IRON

Sample: 1 g of Sodium Ferrous Citrate

Blank: Prepare as directed in the *Analysis* without the *Sample*.

Titrimetric system

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

Mode: Direct titration

Titrant: [0.1 N sodium thiosulfate VS](#)

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a flask with a ground-glass stopper. Carefully add 25 mL of 5% [sulfuric acid](#) and 2 mL of [nitric acid](#) to the flask, and boil the mixture for 10 min. Allow the mixture to cool to room temperature. Add 20 mL of water and 4 g of [potassium iodide](#), and immediately close the flask tightly with the stopper. Allow the mixture to stand in the dark for 15 min, and then add 100 mL of water. Titrate the liberated iodine with *Titrant* (indicator: [starch TS](#)). Perform a blank determination.

Calculate the percentage of iron (Fe) in the portion of the *Sample* taken:

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

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

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

N = actual Titrant normality (mEq/mL)

F = equivalency factor, 55.85 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 10.0%–11.0% on the as-is basis

IMPURITIES

• CHLORIDE AND SULFATE (221), Chloride

Standard solution: 0.10 mL of 0.020 N [hydrochloric acid](#)

Sample: 73 mg of Sodium Ferrous Citrate

Acceptance criteria: NMT 0.1%

• CHLORIDE AND SULFATE (221), Sulfate

Standard solution: 1.0 mL of 0.20 N [sulfuric acid](#)

Sample: 200 mg of Sodium Ferrous Citrate

Acceptance criteria: NMT 0.5%

• FERRIC IRON

Sample: 2.0 g of Sodium Ferrous Citrate

Analysis: Transfer the *Sample* to an appropriate flask with a ground-glass stopper, dissolve in 5 mL of [hydrochloric acid](#), and dilute with water to 30 mL. Add 4 g of [potassium iodide](#) and close the flask with the stopper. Allow the mixture to stand in the dark for 15 min. Add 2 mL of [starch TS](#), and mix well.

Acceptance criteria: A color develops and disappears upon addition of 1.0 mL of [0.1 N sodium thiosulfate VS](#) to the solution.

Change to read:

• ELEMENTAL IMPURITIES—PROCEDURES (233)

Acceptance criteria

Arsenic: NMT 4.0 µg/g

Lead: NMT $\Delta^1 \Delta$ (USP 1-Dec-2020) µg/g

Mercury: NMT 3.0 µg/g

SPECIFIC TESTS

• TARTRATE

Sample: 1.0 g of Sodium Ferrous Citrate

Analysis: Transfer the *Sample* into an appropriate container. Carefully add 5 mL of water and 10 mL of 6.7% (w/v) [potassium hydroxide](#) solution. Heat the mixture in a water bath for 10 min while stirring well. Allow the mixture to cool to room temperature and filter. To 5 mL of the filtrate add 25% [acetic acid](#) solution, to make the mixture weakly acidic, and 2 mL of [acetic acid](#). Allow the solution to stand for 24 h.

Acceptance criteria: No white, crystalline precipitate is formed.

ADDITIONAL REQUIREMENTS

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

• **LABELING:** Label it to indicate that it is not to be used if it is coated with brownish yellow basic ferric sulfate.

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

Topic/Question	Contact	Expert Committee
SODIUM FERROUS CITRATE	Nagaphani Batchu Senior Scientist I, Documentary Standards	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements