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Ferrous Gluconate Tablets

DEFINITION

Ferrous Gluconate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of ferrous gluconate dihydrate ($C_{12}H_{22}FeO_{14} \cdot 2H_2O$).

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHY

Standard solution: 10 mg/mL of [USP Potassium Gluconate RS](#)

Sample solution: A filtered solution in water, equivalent to 10 mg/mL of ferrous gluconate dihydrate from powdered Tablets

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 μ L

Developing solvent system: Alcohol, ethyl acetate, ammonium hydroxide, and water (50:10:10:30)

Spray reagent: Dissolve 2.5 g of ammonium molybdate in 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask. Add 1.0 g of ceric sulfate, swirl to dissolve, and dilute with 2 N sulfuric acid to volume.

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry at 110° for 20 min. Allow to cool, and spray with *Spray reagent*. Heat the plate at 110° for about 10 min.

Acceptance criteria: The principal spot of the *Sample solution* corresponds in color, size, and R_f value to that of the *Standard solution*.

• B. FERROUS ION

Sample solution: Equivalent to 5 mg/mL of ferrous gluconate dihydrate from a dilution of the *Sample solution* obtained in *Identification* test A

Analysis: Add potassium ferricyanide TS to the *Sample solution*.

Acceptance criteria: The solution yields a dark blue precipitate.

ASSAY

• PROCEDURE

Sample: A portion of the powder from NLT 20 finely powdered Tablets, equivalent to 1.5 g of ferrous gluconate dihydrate

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

Titrimetric system

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

Mode: Direct titration

Titrant: 0.1 N ceric sulfate VS

Indicator: Orthophenanthroline TS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in a mixture of 75 mL of water and 15 mL of 2 N sulfuric acid in a 300-mL conical flask. Add 250 mg of zinc dust, close the flask with a stopper containing a Bunsen valve, and allow to stand at room temperature for 20 min or until the solution becomes colorless. Pass the solution through a filtering crucible containing a thin layer of zinc dust, and wash the crucible and contents with 10 mL of 2 N sulfuric acid, followed by 10 mL of water.

[NOTE—Prepare and use the filtering crucible in a well-ventilated hood.]

Add orthophenanthroline TS, and immediately titrate the filtrate in the suction flask with *Titrant* until color change. Perform a *Blank* determination.

Calculate the percentage of the labeled amount of ferrous gluconate dihydrate ($C_{12}H_{22}FeO_{14} \cdot 2H_2O$) in the portion of Tablets 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 normality of the *Titrant* (mEq/mL)

F = equivalency factor, 482.2 mg/mEq

W = nominal amount of ferrous gluconate dihydrate in the *Sample* taken (mg)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: Simulated gastric fluid TS; 900 mL

Apparatus 2: 150 rpm

Time: 80 min

Standard solution: Solution having a known concentration of iron in the *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with the *Medium* if necessary

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 248.3 nm

Lamp: Iron hollow-cathode

Flame: Air–acetylene

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the concentration of iron (Fe) in the *Sample solution* in comparison with a *Standard solution*.

Calculate the percentage of the labeled amount of ferrous gluconate dihydrate ($C_{12}H_{22}FeO_{14} \cdot 2H_2O$) dissolved:

$$\text{Result} = (M_r/A_r) \times (C \times D \times V/L) \times 100$$

M_r = molecular weight of ferrous gluconate dihydrate, 482.17

A_r = atomic weight of iron, 55.85

C = measured concentration of iron in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label amount of ferrous gluconate dihydrate (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of ferrous gluconate dihydrate ($C_{12}H_{22}FeO_{14} \cdot 2H_2O$) is dissolved.

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

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

• **LABELING:** Label the Tablets in terms of the content of ferrous gluconate dihydrate ($C_{12}H_{22}FeO_{14} \cdot 2H_2O$) and in terms of the content of elemental iron.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Potassium Gluconate RS](#)

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

Topic/Question	Contact	Expert Committee
FERROUS GLUCONATE TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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