

Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-D72E2821-B4CB-4BE5-9B48-D29A0D9897F7_2_en-US
DOI: https://doi.org/10.31003/USPNF_M32970_02_01
DOI Ref: 2zqc1

© 2025 USPC
Do not distribute

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

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-D72E2821-B4CB-4BE5-9B48-D29A0D9897F7_2_en-US

Previous DocID: GUID-D72E2821-B4CB-4BE5-9B48-D29A0D9897F7_1_en-US

DOI: https://doi.org/10.31003/USPNF_M32970_02_01

DOI ref: [2zqc1](#)

OFFICIAL