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Ferrous Gluconate Capsules

DEFINITION

Ferrous Gluconate Capsules 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 the contents of the Capsules

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

Buffer: Dissolve 3.0 g of sodium acetate in 50 mL of water. Add 2.0 mL of glacial acetic acid, dilute with water to 200 mL, and mix. This *Buffer* has a pH of 4.6.

Color reagent solution: Dissolve 400 mg of 2,2'-bipyridine in 100 mL of water, using heat if necessary, to dissolve. Cool, and filter.

Standard stock solution: 7.022 mg/mL of ferrous ammonium sulfate hexahydrate [$Fe(NH_4)_2(SO_4)_2 \cdot 6H_2O$] in water, equivalent to 1000 μ g/mL of iron (Fe)

Standard solution: 100 μ g/mL of iron (Fe) in 0.1 N sulfuric acid from *Standard stock solution*

Sample solution

For hard gelatin capsules: Transfer, as completely as possible, the contents of NLT 20 Capsules to a suitable tared container. Mix and finely powder the combined contents, and transfer a weighed portion of the powder, equivalent to 430 mg of ferrous gluconate dihydrate, to a 500-mL volumetric flask. Add 300 mL of water, heating on a steam bath if necessary to dissolve. Cool, and dilute with water to volume.

For soft gelatin capsules: Place a number of Capsules, equivalent to 430 mg of ferrous gluconate dihydrate, in a 500-mL volumetric flask. Add 300 mL of water, heating on a steam bath to dissolve the Capsules. Cool, and dilute with water to volume.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 522 nm

Cell: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Transfer 3.0 mL of the *Sample solution* to a 100-mL volumetric flask, and add, in the order named, 70 mL of *Buffer*, 10.0 mL of 100 mg/mL of sodium thiosulfate solution, and 5.0 mL of *Color reagent solution*, with mixing following each addition. Heat for 60 min on a steam bath, cool, dilute with *Buffer* to volume, and filter. Prepare reagent blanks for the *Standard solution* and the *Sample solution* by repeating the above procedure, omitting the addition of 5.0 mL of *Color reagent solution*.

Concomitantly determine the absorbances of the reacted solutions against the corresponding reagent blanks.

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

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_r/A_r) \times 100$$

A_U = absorbance of the *Sample solution* corrected by the absorbance of its reagent blank

A_S = absorbance of the *Standard solution* corrected by the absorbance of its reagent blank

C_S = concentration of iron in the *Standard solution* ($\mu\text{g/mL}$)

C_U = nominal concentration of ferrous gluconate dihydrate in the *Sample solution* ($\mu\text{g/mL}$)

M_r = molecular weight of ferrous gluconate dihydrate, 482.17

A_r = atomic weight of iron, 55.85

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 45 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/Capsule)

Tolerances: NLT 75% (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 Capsules 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 CAPSULES	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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