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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  $\mu$ 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  $\mu$ g/mL of iron (Fe)

**Standard solution:** 100  $\mu$ 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* ( $\text{mg/mL}$ )

$D$  = dilution factor for the *Sample solution*

$V$  = volume of *Medium*, 900 mL

$L$  = label amount of ferrous gluconate dihydrate ( $\text{mg/Capsule}$ )

**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	<a href="#">Natalia Davydova</a> Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. Information currently unavailable

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