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Ferrous Gluconate Oral Solution

DEFINITION

Ferrous Gluconate Oral Solution contains NLT 94.0% and NMT 106.0% 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 in water

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

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 µL

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 in water 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: An accurately measured volume of Oral Solution, equivalent to 1.2 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 cooled mixture of 80 mL of recently boiled water and 80 mL of 2 N sulfuric acid. Add orthophenanthroline TS, and immediately titrate with *Titrant* until a change in color. 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 Oral Solution 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: 94.0%–106.0%

OTHER COMPONENTS

• **Alcohol Determination ⟨611⟩:** 6.3%–7.7% of C_2H_5OH

SPECIFIC TESTS

• **pH ⟨791⟩:** 3.4–3.8

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **Labeling:** Label the Oral Solution 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 ORAL SOLUTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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