U.S. PHARMACOPEIA

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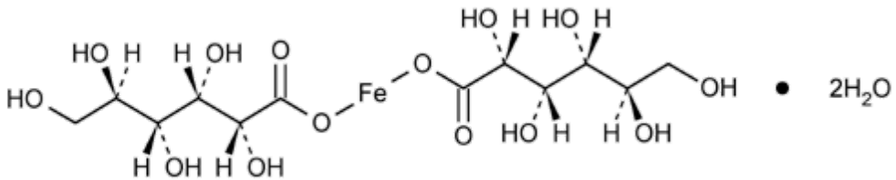
Ferrous Gluconate



$C_{12}H_{22}FeO_{14}\cdot 2H_2O$ 482.17

D-Gluconic acid, iron(2+) salt (2:1), dihydrate.
Iron(2+) gluconate (1:2) dihydrate [*12389-15-0*].

Anhydrous 446.15 [*299-29-6*].

» Ferrous Gluconate contains not less than 97.0 percent and not more than 102.0 percent of $C_{12}H_{22}FeO_{14}$, calculated on the dried basis.

Packaging and storage— Preserve in tight containers.

USP Reference standards ⟨ 11 ⟩ **—** *USP Potassium Gluconate RS*.

Identification—

A: It responds to *Identification* test *B* under *Calcium Gluconate*.

B: A solution (1 in 200) yields a dark blue precipitate with potassium ferricyanide TS.

Loss on drying ⟨ 731 ⟩ **—** Dry it at 105° for 16 hours: it loses between 6.5% and 10.0% of its weight.

Chloride ⟨ 221 ⟩ **—** A 1.0-g portion shows no more chloride than corresponds to 1.0 mL of 0.020 N hydrochloric acid (0.07%).

Oxalic acid— Dissolve 1.0 g in 10 mL of water, add 2 mL of hydrochloric acid, and transfer to a separator. Extract successively with 50 mL and 20 mL of ether. Combine the ether extracts, add 10 mL of water, and evaporate the ether on a steam bath. Add 1 drop of 6 N acetic acid and 1 mL of calcium acetate solution (1 in 20): no turbidity is produced within 5 minutes.

Sulfate ⟨ 221 ⟩ **—** A 1.0-g portion shows no more sulfate than corresponds to 1.0 mL of 0.020 N sulfuric acid (0.1%).

Arsenic, *Method I* ⟨ 211 ⟩ **—** Transfer 1.0 g of Ferrous Gluconate to a 100-mL, round-bottom flask fitted with a 24/40 standard-taper joint. Add 40 mL of 9 N sulfuric acid and 2 mL of potassium bromide solution (3 in 10). Immediately connect to a suitable distillation apparatus having a reservoir with a water jacket, cooled with circulating ice water, and heat to dissolve the test specimen. Distill, collect 25 mL of distillate, and transfer the distillate to the arsine generator flask. Wash the condenser and reservoir several times with small portions of water, add the washings to the distillate in the generator flask, add bromine TS until the solution is slightly yellow, and dilute with water to 35 mL. Proceed as directed for *Procedure:* the limit is 3 ppm.

Limit of ferric iron— Dissolve about 5 g, accurately weighed, in a mixture of 100 mL of water and 10 mL of hydrochloric acid, and add 3 g of potassium iodide. Shake, and allow to stand in the dark for 5 minutes. Titrate any liberated iodine with 0.1 N sodium thiosulfate VS, adding 3 mL of starch TS as the endpoint is approached. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N sodium thiosulfate is equivalent to 5.585 mg of ferric iron. Ferrous Gluconate contains not more than 2.0% of ferric iron.

Limit of lead— [NOTE—For the preparation of all aqueous solutions and for the rinsing of glassware before use, employ water that has been passed through a strong-acid, strong-base, mixed-bed ion-exchange resin before use. Select all reagents to have as low a content of lead as practicable, and store all reagent solutions in containers of borosilicate glass. Clean glassware before use by soaking in warm 8 N nitric acid for 30 minutes and by rinsing with deionized water.]

Ascorbic acid–sodium iodide solution— Dissolve 20 g of ascorbic acid and 38.5 g of sodium iodide in water in a 200-mL volumetric flask, dilute with water to volume, and mix.

Trioctylphosphine oxide solution— [*Caution—This solution causes irritation. Avoid contact with eyes, skin, and clothing. Take special precautions in disposing of unused portions of solutions to which this reagent is added.*] Dissolve 5.0 g of trioctylphosphine oxide in 4-methyl-2-pentanone in a 100-mL volumetric flask, dilute with the same solvent to volume, and mix.

Standard solution and *Blank*— Transfer 5.0 mL of *Lead Nitrate Stock Solution*, prepared as directed in the test for *Heavy Metals* ⟨ 231 ⟩, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 2.0 mL of the resulting solution to a 50-mL volumetric flask. To this volumetric flask and to a second, empty 50-mL volumetric flask *(Blank)* add 10 mL of 9 N hydrochloric acid and about 10 mL of water. To each flask add 20 mL of *Ascorbic acid–sodium iodide solution* and 5.0 mL of *Trioctylphosphine oxide solution,* shake for 30 seconds, and allow to separate. Add water to bring the organic solvent layer into the neck of each flask, shake again, and allow to separate. The organic solvent layers are the *Blank* and the *Standard solution,* and they contain 0.0 and 2.0 µg of lead per mL, respectively.

Test solution— Add 1.0 g of Ferrous Gluconate, 10 mL of 9 N hydrochloric acid, about 10 mL of water, 20 mL of *Ascorbic acid–sodium iodide solution,* and 5.0 mL of *Trioctylphosphine oxide solution* to a 50-mL volumetric flask, shake for 30 seconds, and allow to separate. Add water to bring the organic solvent layer into the neck of the flask, shake again, and allow to separate. The organic solvent layer is the *Test solution.*

Procedure— Concomitantly determine the absorbances of the *Blank,* the *Standard solution,* and the *Test solution* at the lead emission line at 283.3 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* ⟨ 851 ⟩) equipped with a lead hollow-cathode lamp and an air–acetylene flame, using the *Blank* to set the instrument to zero. In a suitable analysis, the absorbance of the *Standard solution* and the absorbance of the *Blank* are significantly different: the absorbance of the *Test solution* does not exceed that of the *Standard solution* (0.001%).

Mercury ⟨ 261 ⟩**:** 3 ppm.

Reducing sugars— Dissolve 500 mg in 10 mL of water, warm, and render alkaline with 1 mL of 6 N ammonium hydroxide. Pass hydrogen sulfide gas into the solution to precipitate the iron, and allow the solution to stand for 30 minutes to coagulate the precipitate. Filter, and wash the precipitate with two successive 5-mL portions of water. Acidify the combined filtrate and washings with hydrochloric acid, and add 2 mL of 3 N hydrochloric acid in excess. Boil the solution until the vapors no longer darken lead acetate paper, and continue to boil, if necessary, until it has been concentrated to about 10 mL. Cool, add 5 mL of sodium carbonate TS and 20 mL of water, filter, and adjust the volume of the filtrate to 100 mL. To 5 mL of the filtrate add 2 mL of alkaline cupric tartrate TS, and boil for 1 minute: no red precipitate is formed within 1 minute.

Organic volatile impurities, *Method I* ⟨ 467 ⟩**:** meets the requirements.

Residual solvents ⟨ 467 ⟩**:** meets the requirements.
(Official January 1, 2007)

Assay— Dissolve about 1.5 g of Ferrous Gluconate, accurately weighed, 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 minutes 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 0.1 N ceric sulfate VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N ceric sulfate is equivalent to 44.61 mg of $C_{12}H_{22}FeO_{14}$.

Auxiliary Information— *Staff Liaison* : Lawrence Evans, III, Ph.D., Scientist
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