

# FERROUS GLUCONATE

Prepared at the 53rd JECFA (1999) and published in FNP 52 Add 7 (1999), superseding specifications prepared at the 51st JECFA (1998), published in FNP 52 Add 6 (1998). PMTDI 0.8 mg/kg bw for iron, established at the 27th JECFA in 1983.

## SYNONYMS

INS No. 579

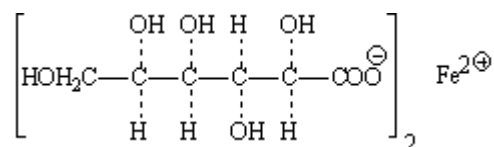
## DEFINITION

Chemical names Iron (II) di-D-gluconate dihydrate, ferrous gluconate

C.A.S. number 299-29-6

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

Structural formula



Formula weight 482.17

Assay Not less than 95% on the dried basis

## DESCRIPTION

Fine yellowish-grey or pale greenish-yellow powder or granules having a slight odour resembling that of burnt sugar

**FUNCTIONAL USES** Colour, stabilizer, nutrient supplement

## CHARACTERISTICS

### IDENTIFICATION

Solubility (Vol. 4) Soluble with slight heating in water; practically insoluble in ethanol

Test for ferrous salts (Vol. 4) Passes test

Test for gluconate (Vol.4) Passes test

### PURITY

Loss on drying (Vol. 4) Not less than 6.5% and not more than 10.0% (105°, 16 h)

Reducing sugars Dissolve 0.5 g of the sample in 10 ml of water; warm, and make the solution alkaline with 1 ml of ammonia TS. Pass hydrogen sulfide gas into the solution to precipitate the iron, and allow the mixture to stand for 30 min 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 dilute hydrochloric acid TS in excess. Boil the solution until the vapours no longer darken lead acetate paper, and continue to boil, if necessary, until concentrated to about 10 ml. Allow to 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 min. No red precipitate should be formed within 1 min.

Iron (III)

Not more than 2%

Dissolve about 5 g of the sample, accurately weighed, in a mixture of 100 ml of water and 10 ml of hydrochloric acid in a 250-ml glass stoppered flask. Add 3 g of potassium iodide, shake well, and allow to stand in the dark for 5 min. Titrate any liberated iodine with 0.1 N sodium thiosulfate, using starch TS as the indicator. Each ml of 0.1 N sodium thiosulfate is equivalent to 5.585 mg of iron (Fe III).

Lead (Vol. 4)

Not more than 2 mg/kg

Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, "Instrumental Methods."

**METHOD OF ASSAY**

Dissolve about 1.5 g of the dried sample, accurately weighed, in a mixture of 75 ml of water and 15 ml of dilute sulfuric acid TS in a 300-ml Erlenmeyer flask, and 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. Then filter through a Gooch crucible containing a glass fibre filter paper coated with a thin layer of zinc dust, and wash the crucible and contents with 10 ml of dilute sulfuric acid TS, followed by 10 ml of water. Add orthophenanthroline TS and titrate the filtrate in the suction flask immediately with 0.1 N ceric sulfate. Perform a blank determination, and make any necessary correction. Each ml of 0.1 N ceric sulfate is equivalent to 44.61 mg of  $C_{12}H_{22}FeO_{14}$ .