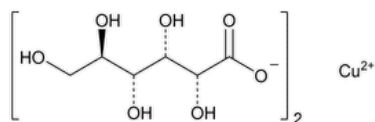


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Copper Gluconate



$C_{12}H_{22}CuO_{14}$ 453.84

Copper, bis(*D*-gluconato- O^1,O^2)-;

Copper *D*-gluconate (1:2) CAS RN®: 527-09-3; UNII: RV823G6G67.

DEFINITION

Copper Gluconate contains NLT 98.0% and NMT 102.0% of copper gluconate ($C_{12}H_{22}CuO_{14}$).

IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL, [Copper\(191\)](#):** A 50-mg/mL solution meets the requirements.

• **B. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST**

Standard solution: 10 mg/mL of [USP Potassium Gluconate RS](#)

Sample solution: 10 mg/mL of Copper Gluconate, heating in a water bath at 60°, if necessary, to dissolve

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 the *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*.

ASSAY

PROCEDURE

Sample: 1.5 g of Copper Gluconate

Blank: 100 mL of water

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Indirect titration

Titrant: 0.1 N sodium thiosulfate VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 100 mL of water. Add 2 mL of glacial acetic acid and 5 g potassium iodide, mix, and titrate with *Titrant* to a light yellow color. Add 2 g of ammonium thiocyanate, and mix. Add 3 mL of starch TS, and continue titrating to a milk-white endpoint.

Perform the blank determination.

Calculate the percentage of copper gluconate ($C_{12}H_{22}CuO_{14}$) in the *Sample* 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, 453.8 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• [CHLORIDE AND SULFATE, Chloride\(221\)](#)

Standard solution: 1.0 mL of 0.020 N hydrochloric acid

Sample: 1.0 g

Acceptance criteria: NMT 0.07%

• [CHLORIDE AND SULFATE, Sulfate\(221\)](#)

Standard solution: 1.0 mL of 0.020 N sulfuric acid

Sample: 2.0 g

Acceptance criteria: NMT 0.05%

Change to read:

• [▲ ARSENIC \(211\), Procedures, Procedure 1 ▲](#) (CN 1-JUN-2023)

Test preparation: 1.0 g in 35 mL of water

Acceptance criteria: NMT 3 ppm

• LIMIT OF LEAD

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

Standard stock solution: Transfer 10.0 mL of lead nitrate stock solution TS to a 100-mL volumetric flask. Add 40 mL of water and 5 mL of nitric acid, and dilute with water to volume.

Standard solution: Transfer 0.40 mL of *Standard stock solution* to a 100-mL volumetric flask. Add 50 mL of water and 1 mL of nitric acid, and dilute with water to volume. This solution contains 0.04 µg/mL of lead.

Sample stock solution: Transfer 4 g of Copper Gluconate to a 100-mL volumetric flask. Add 50 mL of water and 5 mL of nitric acid, and sonicate to dissolve the specimen. Dilute with water to volume. Transfer 4.0 mL of this solution to a second 100-mL volumetric flask. Add 50 mL of water and 1 mL of nitric acid, dilute with water to volume, and mix.

Blank: Transfer 1.2 mL of nitric acid to a 100-mL volumetric flask and dilute with water to volume.

Sample solution A: Mix 10.0 mL of the *Sample stock solution* with 10.0 mL of *Blank*. This solution contains 0.00 µg/mL of added lead from the *Standard solution*.

Sample solution B: Mix 10.0 mL of the *Sample stock solution* with 4.0 mL of the *Standard solution* and 6.0 mL of *Blank*. This solution contains 0.008 µg/mL of added lead from the *Standard solution*.

Sample solution C: Mix 10.0 mL of the *Sample stock solution* with 7.0 mL of the *Standard solution* and 3.0 mL of *Blank*. This solution contains 0.014 µg/mL of added lead from the *Standard solution*.

Sample solution D: Mix 10.0 mL of the *Sample stock solution* with 10.0 mL of the *Standard solution*. This solution contains 0.020 µg/mL of added lead from the *Standard solution*.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Graphite furnace atomic absorption spectrophotometry

Analytical wavelength: 283.3 nm

Lamp: Lead hollow-cathode

Argon flow rate: 3 L/min, or as noted

Graphite tube temperature: See [Table 1](#).

Table 1