U.S. PHARMACOPEIA

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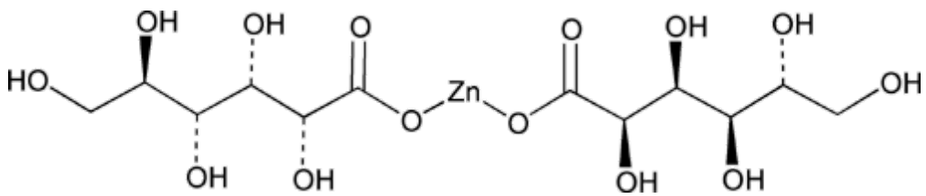
Zinc Gluconate



$C_{12}H_{22}O_{14}Zn$ 455.68

Bis(D-gluconato-O^1,O^2) zinc.
Zinc D-gluconate (1:2) [*4468-02-4*].

» Zinc Gluconate contains not less than 97.0 percent and not more than 102.0 percent of $C_{12}H_{22}O_{14}Zn$, calculated on the anhydrous basis.

Packaging and storage— Preserve in well-closed containers.

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

Identification—

A: A solution (1 in 10) responds to the tests for *Zinc* ⟨ 191 ⟩.

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

pH ⟨ 791 ⟩ **:** between 5.5 and 7.5, in a solution (1 in 100).

Water, *Method Ib* ⟨ 921 ⟩ **:** not more than 11.6%.

Chloride ⟨ 221 ⟩ **—** A 1.0-g portion shows no more chloride than corresponds to 0.70 mL of 0.020 N hydrochloric acid (0.05%).

Sulfate ⟨ 221 ⟩ **—** A 2.0-g portion shows no more sulfate than corresponds to 1.0 mL of 0.020 N sulfuric acid (0.05%).

Arsenic, *Method I* ⟨ 211 ⟩ **—** Dissolve 1.0 g in 35 mL of water: the limit is 3 ppm.

Reducing substances— Transfer 1.0 g to a 250-mL conical flask, dissolve in 10 mL of water, and add 25 mL of alkaline cupric citrate TS. Cover the flask, boil gently for 5 minutes, accurately timed, and cool rapidly to room temperature. Add 25 mL of 0.6 N acetic acid, 10.0 mL of 0.1 N iodine VS, and 10 mL of 3 N hydrochloric acid, and titrate with 0.1 N sodium thiosulfate VS, adding 3 mL of starch TS as the endpoint is approached. Perform a blank determination, omitting the specimen, and note the difference in volumes required. Each mL of the difference in volume of 0.1 N sodium thiosulfate consumed is equivalent to 2.7 mg of reducing substances (as dextrose): the limit is 1.0%.

Limit of cadmium—

Standard preparation— Transfer 137.2 mg of cadmium nitrate to a 1000-mL volumetric flask, dissolve in water, dilute with water to volume, and mix. Pipet 25 mL of the resulting solution into a 100-mL volumetric flask, add 1 mL of hydrochloric acid, dilute with water to volume, and mix. Each mL of this *Standard preparation* contains 12.5 µg of Cd.

Test preparation— Transfer 10.0 g of Zinc Gluconate to a 50-mL volumetric flask, dissolve in and dilute with water to volume, and mix.

Procedure— To three separate 25-mL volumetric flasks add, respectively, 0, 2.0, and 4.0 mL of the *Standard preparation.* To each flask add 5.0 mL of the *Test preparation,* dilute with water to volume, and mix. These test solutions contain, respectively, 0, 1.0, and 2.0 µg per mL of cadmium from the *Standard preparation.* Concomitantly determine the absorbances of the test solutions at the cadmium emission line at 228.8 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-scattering* ⟨ 851 ⟩) equipped with a cadmium hollow-cathode lamp and an air–acetylene flame, using water as the blank. Plot the absorbances of the test solutions versus their contents of cadmium, in µg per mL, as furnished by the *Standard preparation,* draw the straight line best fitting the three points, and extrapolate the line until it intercepts the concentration axis. From the intercept determine the amount, in µg, of cadmium in each mL of the test solution containing 0 mL of the *Standard preparation.* Calculate the quantity, in ppm, of Cd in the specimen by multiplying this value by 25: the limit is 5 ppm.

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. Cleanse 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 µg and 2.0 µg of lead per mL, respectively.

Test solution— Add 1.0 g of Zinc 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, Standard solution,* and *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%).

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

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.

(Official January 1, 2007)

Assay— Dissolve about 700 mg of Zinc Gluconate, accurately weighed, in 100 mL of water. Add 5 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS until the solution is deep blue in color. Each mL of 0.05 M edetate disodium is equivalent to 22.78 mg of $C_{12}H_{22}O_{14}Zn$.

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