Zinc Gluconate

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

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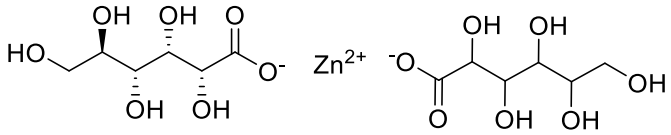
Zinc Gluconate



$C_{12}H_{22}O_{14}Zn$ Mol. Wt. 455.7

Zinc Gluconate is Bis(D-gluconato-O^1, O^2) zinc.

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

Category. Zinc replenisher.

Description. A white powder or granules.

Identification

A. A 10 per cent w/v solution gives the reaction of zinc salts.

B. Determine by thin-layer chromatography (2.4.17), coating the plate with silica gel G.

Test solution. Dissolve 1.0 g of the substance under examination in the *water* and dilute to 100.0 ml with the *water*. Heating in a water-bath at 60°, if necessary, to dissolve.

Reference solution. A 1.0 per cent w/v solution of *potassium gluconate IPRS* in *water.*

Spray reagent. Dissolve 2.5 g of *ammonium molybdate* in 50 ml of *1 M sulphuric acid* in a 100-ml volumetric flask, add 1.0 g of *ceric sulphate*, swirl to dissolve, and dilute to volume with *1 M sulphuric acid.*

Mobile phase. a mixture of 50 volumes of *alcohol (95 per cent),* 10 volumes of *ethyl acetate,* 10 volumes of *ammonium hydroxide,* and 30 volumes of *water.*

Apply to the plate 5 µl of the reference solution and the test solution. After development, dry the plate in a current of air, place the plate in a suitable chromatographic chamber, and develop the chromatogram, using mobile phase, until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, and allow it to dry at 110° for 20 minutes. Allow to cool, and spray the plate with spray reagent. Dry the plate at 110° for about 10 minutes. The principal spot in the chromatogram obtained with the test solution corresponds in color, size, and RF value to that of the reference solution.

Tests

pH (2.4.24). 5.5 to 7.5, determined in a 1.0 per cent w/v solution.

Chlorides (2.3.12). 0.5 g complies with the limit test for chlorides (500 ppm).

Sulphates (2.3.17). 0.3 g complies with the limit test for sulphates (500 ppm).

Arsenic (2.3.10). Dissolve 3.33 g in 35 ml of *water.* The resulting solution complies with the limit test for arsenic (3 ppm).

Lead. Not more than 10 ppm, determine by atomic absorption spectrophotometry (2.4.2), measuring at 283.3 nm using an air-acetylene flame and lead hollow-cathode lamp.

[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 4 M nitric acid for 30 minutes and by rinsing with deionized water.]

Solution A. A solution containing 10 per cent w/v of *ascorbic acid* and 19.25 per cent w/v of *sodium iodide* in *water*.

Solution B. A 5 per cent w/v solution of *trioctylphosphine oxide* in *4-methyl-2-pentanone*.

[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.]

Blank solution. To a 50-ml volumetric flask add 10 ml of *9 M hydrochloric acid*, 10 ml of *water*, 20 ml of solution A, and 5.0 ml of solution B. 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. Use the organic layer as the blank solution.

Test solution. To a 50-ml volumetric flask add 1.0 g of substance under examination, 10 ml of *9 M hydrochloric acid*, 10 ml of *water*, 20 ml of solution A, and 5.0 ml of solution B. 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. Use the organic layer as the test solution.

Reference solution. To 5.0 ml of *lead nitrate stock solution*, to a 100-ml volumetric flask, and dilute with *water* to volume. Transfer 2.0 ml of the solution to a 50-ml volumetric flask, and add 10 ml of *9 M hydrochloric acid* and 10 ml of *water*. Add 20 ml of solution A and 5.0 ml of solution B. 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. Use organic layer as the reference solution. It contains 2 ppm of lead.

Concomitantly determine the determine the absorbances of the blank, reference solution and the test solution. Use the blank to set the instrument to zero.

Limit of Cadmium. Not more than 5 ppm, determine by atomic absorption spectrophotometry (2.4.2), measuring at 228.8 nm using an air-acetylene flame and cadmium hollow-cathode lamp.

Reference solution. A 0.01372 per cent w/v solution of *cadmium nitrate* in *water*. Transfer 25.0 ml of the solution in to a 100-ml volumetric flask, add 1 ml of *hydrochloric acid* and dilute to volume with *water*. It contains 12.5 ppm of cadmium.

Test solution (a). Dissolve 10 g of the substance under examination in the *water* and dilute to 50.0 ml with the *water*.

Test solution (b). Transfer 5.0 ml of test solution (a) to a 25- ml volumetric flask and diluted to volume with *water*. [This solution contains 0 ppm of added cadmium].

Test solution (c). Transfer 5.0 ml of test solution (a) to a 25- ml volumetric flask, add 2.0 ml of the reference solution and dilute to volume with *water*. [This solution contains 1.0 ppm of added cadmium].

Test solution (d). Transfer 5.0 ml of test solution (a) to a 25- ml volumetric flask, add 4.0 ml of the reference solution and dilute to volume with *water*. [This solution contains 2.0 ppm of added cadmium].

Determine the absorbance. Correct the absorbance values of test solution (a), test solution (b) and test solution (c) from that of the blank. Plot the corrected absorbance of test solution (a), test solution (b) and test solution (c) versus their added cadmium concentrations, in ppm. 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 ppm, of cadmium in test solution (a).

Calculate the content of cadmium in the portion of zinc gluconate, using the following expression;

$$\text{Result} = (C \times V)/W$$

Where,

C = concentration of cadmium in test solution (a) (ppm), determined from the intercept of the linear regression line

V = volume of solvent taken to prepare test solution (a) (ml)

W = weight of substance taken to prepare test solution (a) (g)

Reducing substances. Not more than 1.0 per cent.

Dissolve 1.0 g of substance under examination in 10 ml of *water* in a 25-ml conical flask. Add 25 ml of *alkaline cupric citrate*. Cove the flask, boil gently for 5 minutes, accurately timed, and cool rapidly to room temperature. Add 25 ml of *0.6 M acetic acid*, 10 ml of *0.05 M iodine* and 10 ml of *3 M hydrochloric acid*. Titrate the excess of iodine with *0.1 M sodium thiosulphate*, using 3 ml of *starch solution* added towards the end of the titration, as indicator. Carry out a blank titration.

Calculate the percentage of reducing substances (as dextrose) in the test taken:

$$\text{Result} = \{[(VB - VS) \times M \times F]/W\} \times 100$$

Where,

VB = Consumed by the blank (ml)
VS = Volume of *0.1 M sodium thiosulphate* consumed by the test (ml)
M = Molarity of *0.1 M sodium thiosulphate*
F = equivalency factor, 27 mg/mEq
W = Test weight (mg)

Water (2.3.43). Not more than 11.6 per cent.

Assay. Dissolve 0.7 g of the substance under examination in 100 ml of *water*. Add 5 ml of *ammonia-ammonium chloride buffer* and 0.1 ml of *eriochrome black* and titrate with 0.05 M disodium edentate until the solution is deep blue in colour. Carry out a blank titration.

1 ml of *0.05 M disodium edetate* is equivalent to 0.022579 g of zinc gluconate, $C_{12}H_{22}O_{14}Zn$.

Storage. Store protected from moisture, at a temperature not exceeding 30°.

Solubility.

Zinc Gluconate. Soluble in *water*; very slightly soluble in *ethanol (95 per cent)*.