Zinc Gluconate Tablets

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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 Tablets

Zinc Gluconate tablets contain not less than 93.0 per cent and not more than 107.0 per cent of the stated amount of zinc, Zn, in the form of zinc gluconate, $C_{12}H_{22}O_{14}Zn$.

Usual strengths. 25 mg; 30 mg; 50 mg; 100 mg.

Identification

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

Test solution. Disperse a quantity of the powdered tablets containing 1.0 g of the Zinc Gluconate in *water* with the aid of ultrasound with intermittent shaking and dilute to 100.0 ml with the *water*. Heating in a water-bath at 60°, if necessary and filter.

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 in the chromatogram obtained with the reference solution.

B. *Solution (a)*. A 4.2 per cent w/v solution of *sodium hydroxide* in *water.*

Solution (b). A 10.7 per cent w/v solution of *ammonium chloride* in *water.*

Solution (c). A mixture of 85 volumes of *glycerin* and 15 volumes of *water.*

Solution (d). A mixture of 29 volumes of solution (c) and 10 volumes of *water.*

Solution (e). Dissolve 12 g of *sodium sulphide* with heating in a 45 ml of solution (d), allow to cool and dilute to 100.0 ml with solution (d).

Test solution. Disperse a quantity of the powdered tablets containing 1.0 g of the Zinc Gluconate in *water* with the aid of ultrasound with intermittent shaking and dilute to 10.0 ml with *water*. Heating in a water-bath at 60°, if necessary and filter.

To 5 ml of the test solution add 0.2 ml of solution (a), add an additional 2 ml of solution (a), and add 10 ml of solution (b). Add 0.1 ml of solution (e); A white precipitate is formed after the first addition of solution (a). The precipitate dissolves after the second addition of solution (a). The solution remains clear after addition of solution (b), and a white precipitate forms after addition of solution (e).

Tests

Disintegration (2.5.1). *(For tablets intended to be mixed with water prior to intake as oral liquids)* Not more than 60 seconds.

Dissolution (2.5.2). *(For tablets not to be mixed with water prior to indigestion).*
Apparatus No. 2 (Paddle),
Medium. 900 ml of a *0.01 M hydrochloric acid*,
Speed and time. 50 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter. Determine by atomic absorption spectrophotometry (2.4.2) at the resonance emission line for zinc at 213.8 nm. Calculate the amount of $C_{12}H_{22}O_{14}Zn$ dissolved on filtered portions of the solution, suitably diluted with *water* in comparison with a solution of known concentration of *zinc gluconate IPRS* in the same medium.

Q. Not less than 75 per cent of the stated amount of $C_{12}H_{22}O_{14}Zn$.

Other tests. Comply with the tests stated under Tablets.

Assay. Weigh and powder 20 tablets. Transfer a quantity of the powdered tablets containing 80 mg of Zinc to a suitable crucible, and ignite, gently until free from carbon. Cool the crucible, add 25 ml of *water* and 5 ml of *hydrochloric acid*, and stir. Heat on a steam bath for 5 minutes and filter, rinsing the filter with several portions of *water*. Dilute the combined filtrate and washes with *water* to about 100.0 ml. Add *ammonia ammonium chloride buffer* until the solution is neutral to *litmus paper*. Add 5 ml of *ammonia ammonium chloride buffer* and 0.1 ml of *eriochrome black T solution*, and titrate with *0.05 M disodium edetate* to a blue colour. Carry out a blank titration.

1 ml of *0.05 M disodium edetate* is equivalent to 0.00327 g of Zn or 0.02278 g of $C_{12}H_{22}O_{14}Zn$.

Storage. Store protected from light and moisture.

Labeling. The label states (I) the strength in terms of elemental zinc and also in terms of zinc gluconate. (II) Whether the tablets are intended to be mixed with water before intake.
