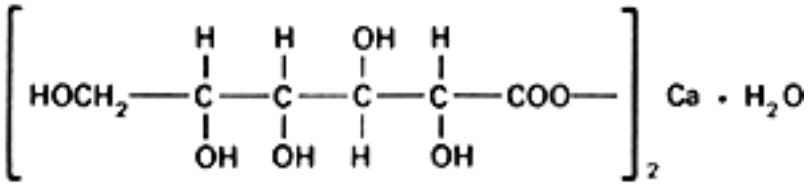
Calcium gluconate (Calcii gluconas)

Molecular formula. $(C_6H_{11}O_7)_2Ca,H_2O$

Relative molecular mass. 448.4

Graphic formula.



Chemical name. Calcium D-gluconate (1:2) monohydrate; CAS Reg. No. 299-28-5.

Description. White, crystalline granules or a white, crystalline powder; odourless.

Solubility. Slowly soluble in water; freely soluble in boiling water; practically insoluble in dehydrated ethanol R and ether R.

Category. Calcium source.

Storage. Calcium gluconate should be kept in a tightly closed container, protected from light.

Additional information. Even in the absence of light, Calcium gluconate is gradually degraded on exposure to a humid atmosphere, the decomposition being faster at higher temperatures.

Requirements

Definition. Calcium gluconate contains not less than 98.0% and not more than 102.0% of $(C_6H_{11}O_7)_2Ca,H_2O$, calculated as the monohydrate.

Identity tests

A. A 20 mg/mL solution yields the reactions described under 2.1 General identification tests as characteristic of calcium.

B. To 1 mL of a 30 mg/mL solution add 1 drop of ferric chloride (25 g/l) TS; a yellow colour is produced.

C. To 5 mL of a warm 0.1 g/mL solution add 0.7 mL of glacial acetic acid R and 1 mL of freshly distilled phenylhydrazine R, heat on a water-bath for 30 minutes, allow to cool, and scrape the inner surface of the tube to induce crystallization. Collect the crystals, dissolve in 10 mL of hot water, add a small amount of charcoal R, and filter. Allow the filtrate to cool, and scrape the inner surface of the tube; a white, crystalline precipitate is produced; melting temperature, about 200°C with decomposition (phenylhydrazide of gluconic acid).

Heavy metals. Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 3; determine the heavy metals content according to Method A; not more than 20 µg/g.

Chlorides and other halides. Dissolve 0.50 g in a mixture of 2 mL of nitric acid (~130 g/l) TS and 20 mL of water, and proceed as described under 2.2.1 Limit test for chlorides; the chloride content is not more than 0.5 mg/g.

Magnesium and alkaline metals. Dissolve 1.0 g in 100 mL of boiling water, add 10 mL of ammonium chloride (100 g/l) TS, 1 mL of ammonia (~260 g/l) TS and, drop by drop, 50 mL of hot ammonium oxalate (25 g/l) TS. Allow to stand for 4 hours, dilute to 200 mL with water and filter. Evaporate 100 mL of the filtrate to dryness and ignite; the residue weighs not more than 2.0 mg.

Sulfates. Dissolve 5.0 g in 40 mL of boiling water, cool and filter. Proceed with the filtrate as described under 2.2.2 Limit test for sulfates; the sulfate content is not more than 0.1 mg/g.

Glucose and sucrose. Dissolve 0.5 g in 10 mL of hot water, add 2 mL of hydrochloric acid (~70 g/l) TS, and boil for about 2 minutes. Cool, add 15 mL of sodium carbonate (50 g/l) TS, allow to stand for 5 minutes, and filter. Add 5 mL of the clear filtrate to about 2 mL of potassio-cupric tartrate TS, and boil for 1 minute; neither a red turbidity nor any precipitate is produced.

Clarity and colour of solution. A solution of 0.50 g in 10 mL of water is clear and not more intensely coloured than standard colour solution Yw1 when compared as described under 1.11.1 Colour of liquids.

Assay. Dissolve about 0.5 g, accurately weighed, in 20 mL of hot water containing 2 mL of hydrochloric acid (~70 g/l) TS, allow to cool and dilute to 100 mL with water. Proceed with the titration as described under 2.5 Complexometric titrations for calcium. Each mL of disodium edetate (0.05 mol/l) VS is equivalent to 22.42 mg of $(C_6H_{11}O_7)_2Ca,H_2O$.

Additional requirements for Calcium gluconate for parenteral use

Complies with the monograph for "Parenteral preparations".

Bacterial endotoxins. Carry out the test as described under 3.4 Test for bacterial endotoxins; contains not more than 167 IU of endotoxin RS per g.