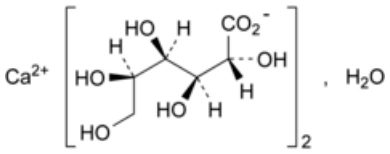
Edition: BP 2025 (Ph. Eur. 11.6 update)

Calcium Gluconate

General Notices

(Ph. Eur. monograph 0172)



$C_{12}H_{22}CaO_{14},H_2O$ 448.4 *18016-24-5*

Action and use

Used in treatment of calcium deficiency.

Preparations

Calcium Gluconate Tablets

Calcium Gluconate Chewable Tablets

Calcium Gluconate Effervescent Tablets

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DEFINITION

Calcium bis[(2*R*,3*S*,4*R*,5*R*)-2,3,4,5,6-pentahydroxyhexanoate] monohydrate (calcium di(D-gluconate) monohydrate).

Content

98.5 per cent to 102.0 per cent of $C_{12}H_{22}CaO_{14},H_2O$.

CHARACTERS

Appearance

White or almost white, crystalline or granular powder.

Solubility

Sparingly soluble in water, freely soluble in boiling water.

IDENTIFICATION

A. Thin-layer chromatography (2.2.27).

Test solution Dissolve 20 mg of the substance to be examined in 1 mL of *water R*, heating if necessary in a water-bath at 60 °C.

Reference solution Dissolve 20 mg of *calcium gluconate CRS* in 1 mL of *water R*, heating if necessary in a water-bath at 60 °C.

Plate *TLC silica gel plate R* (5-40 µm) [or *TLC silica gel plate R* (2-10 µm)].

Mobile phase *concentrated ammonia R*, *ethyl acetate R*, *water R*, *ethanol (96 per cent) R* (10:10:30:50 *V/V/V/V*).

Application 1 µL.

Development Over 2/3 of the plate.

Drying At 100 °C for 20 min; allow to cool.

Detection Spray with a solution containing 10 g/L of *cerium sulfate R* and 25 g/L of *ammonium molybdate R* in *dilute sulfuric acid R* and heat at 105 °C for about 10 min.

Results After 5 min, the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.

B. Solution S (see Tests) gives reaction (b) of calcium (2.3.1).

TESTS

Solution S

Dissolve 1.0 g in *water R* heated to 60 °C and dilute to 50 mL with the same solvent.

Appearance of solution

At 60 °C, solution S is not more intensely coloured than reference solution Y_6 (2.2.2, *Method II*). After cooling, it is not more opalescent than reference suspension II (2.2.1).

Organic impurities and boric acid

Introduce 0.5 g into a porcelain dish previously rinsed with *sulfuric acid R* and placed in a bath of iced water. Add 2 mL of cooled *sulfuric acid R* and mix. No yellow or brown colour develops. Add 1 mL of *chromotrope II B solution R*. A violet colour develops and does not become dark blue. The solution is not more intensely coloured than that of a mixture of 1 mL of *chromotrope II B solution R* and 2 mL of cooled *sulfuric acid R*.

Sucrose and reducing sugars

Dissolve 0.5 g in a mixture of 2 mL of *hydrochloric acid R1* and 10 mL of *water R*. Boil for 5 min, allow to cool, add 10 mL of *sodium carbonate solution R* and allow to stand. Dilute to 25 mL with *water R* and filter. To 5 mL of the filtrate add 2 mL of *cupri-tartaric solution R* and boil for 1 min. Allow to stand for 2 min. No red precipitate is formed.

Chlorides (2.4.4)

Maximum 200 ppm.

Dilute 12.5 mL of solution S to 15 mL with *water R*.

Sulfates (2.4.13)

Maximum 100 ppm.

Dissolve 10.0 g with heating in a mixture of 10 mL of *acetic acid R* and 90 mL of *distilled water R*.

Magnesium and alkali metals

Maximum 0.4 per cent.

Dissolve 1.00 g in 100 mL of boiling *water R*, add 10 mL of *ammonium chloride solution R*, 1 mL of *ammonia R* and, dropwise, 50 mL of hot *ammonium oxalate solution R*. Allow to stand for 4 h, dilute to 200 mL with *water R* and filter. Evaporate 100 mL of the filtrate to dryness and ignite. The residue weighs a maximum of 2 mg.

Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

ASSAY

Dissolve 0.8000 g in 20 mL of hot *water R*, allow to cool and dilute to 300 mL with *water R*. Carry out the complexometric titration of calcium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 44.84 mg of $C_{12}H_{22}CaO_{14},H_2O$.

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