



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

Calcium Gluconate Injection

[General Notices](#)

DEFINITION

Calcium Gluconate Injection is a sterile solution of Calcium Gluconate for Injection in Water for Injections. Not more than 5.0% of the Calcium Gluconate may be replaced with calcium m-saccharate, or other suitable calcium salt, as a stabilising agent.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of calcium, Ca

8.5 to 9.4% of the content of Calcium Gluconate stated on the label.

IDENTIFICATION

- A. To 1 mL add 0.05 mL of [iron\(III\) chloride solution R1](#). An intense yellow colour is produced.
- B. Warm a volume containing the equivalent of 0.5 g of Calcium Gluconate, add 0.65 mL of [glacial acetic acid](#) and 1 mL of [phenylhydrazine](#). Heat on a water bath for 30 minutes, allow to cool and induce crystallisation. Filter, dissolve the residue in 10 mL of hot [water](#), add a few mg of [activated charcoal](#), shake, filter, allow the filtrate to cool and induce crystallisation. A white, crystalline precipitate is produced. The [melting point](#) of the crystals, after drying, is about 200°, with decomposition, [Appendix V A](#).
- C. Yields the reactions characteristic of *calcium salts*, [Appendix VI](#).

TESTS

[Bacterial endotoxins](#)

Carry out the [test for bacterial endotoxins, Appendix XIV C](#). Dilute the injection in [water BET](#) if necessary to give a solution containing 100 mg of Calcium Gluconate per millilitre (solution A). The endotoxin limit concentration of solution A is 16.7 IU per mL.

ASSAY

To a volume containing the equivalent of 0.5 g of Calcium Gluconate add 300 mL of [water](#) and carry out the [complexometric titration of calcium, Appendix VIII D](#), beginning at the words 'add 6 mL of ...'.

LABELLING

The label states (1) the percentage w/v of Calcium Gluconate equivalent to the total amount of calcium present; (2) that solutions containing visible solid particles must not be used; (3) the name and the percentage of any added stabilising

