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

# Calcium Gluconate Tablets

General Notices

## DEFINITION

Calcium Gluconate Tablets contain Calcium Gluconate.

*The tablets comply with the requirements stated under Tablets and with the following requirements.*

**Content of calcium gluconate, $C_{12}H_{22}CaO_{14},H_2O$**

95.0 to 105.0% of the stated amount.

## IDENTIFICATION

A. Extract five tablets, finely powdered, with two 25-mL quantities of *petroleum spirit (boiling range, 40° to 60°)*, discard the extracts and repeat the extraction with three 10-mL quantities of *water*, again discarding the extracts. Dissolve the residue as completely as possible in 30 mL of hot *water*, filter and to 0.5 mL of the filtrate add 0.05 mL of *iron(III) chloride solution R1*. An intense yellow colour is produced.
B. To a volume of the filtrate obtained in test A containing 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, 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 201°, with decomposition, Appendix V A.
C. The powdered tablets yield the reactions characteristic of *calcium salts*, Appendix VI.

## TESTS

**Dissolution**

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1, using Apparatus 2. Use as the medium 900 mL of *water* and rotate the paddle at 50 revolutions per minute. Withdraw a sample of 20 mL of the medium and filter. Carry out the method for *atomic absorption spectrophotometry*, Appendix II D, measuring at 422.7 nm using a calcium hollow-cathode lamp as the radiation source, an air-acetylene flame and the following solutions.

*Test solution* Use the filtered dissolution medium diluted, if necessary, with *water* to give a concentration suitable for the instrument used.

*Standard solutions* Use *calcium standard solution (100 ppm Ca)* suitably diluted with *water*.

Determine the total content of calcium in the dissolution medium and calculate the total content of calcium gluconate taking each mg of calcium to be equivalent to 11.21 mg of $C_{12}H_{22}CaO_{14},H_2O$.

## ASSAY

Weigh and powder 20 tablets. Ignite a quantity of the powder containing 0.5 g of Calcium Gluconate, cool and dissolve the residue with gentle heat in 5 mL of *2M hydrochloric acid*. Filter, wash the residue on the filter with *water* and dilute the combined filtrate and washings to 50 mL with *water*. Neutralise with 5M *ammonia*, using *methyl orange solution* as indicator, add 5 mL of 8M *sodium hydroxide* and titrate with 0.05M *disodium edetate VS* using *calconcarboxylic acid triturate* as indicator. Each mL of 0.05M *disodium edetate VS* is equivalent to 22.42 mg of $C_{12}H_{22}CaO_{14},H_2O$.