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Quality standards

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

Calcium Gluconate Chewable Tablets

General Notices

Chewable Calcium Gluconate Tablets

DEFINITION

Calcium Gluconate Chewable Tablets contain Calcium Gluconate in a Chocolate Basis or other suitable basis with a chocolate flavour.

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

Content of calcium gluconate, C₁₂H₂₂CaO₁₄,H₂O

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. Extract five tablets, finely powdered, with two 25-mL quantities of <u>petroleum spirit</u> (boiling range, 40° to 60°), discard the extracts and repeat the extraction with three 10-mL quantities of <u>water</u>, again discarding the extracts. Dissolve the residue as completely as possible in 30 mL of hot <u>water</u>, filter and to 0.5 mL of the filtrate add 0.05 mL of <u>iron(III) chloride</u> <u>solution R1</u>. 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

Disintegration

The requirement for Disintegration does not apply to Calcium Gluconate Chewable Tablets.

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 $C_{12}H_{22}CaO_{14},H_2O$.

