Quality standards

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Calcium Gluconate Effervescent Tablets

General Notices

Effervescent Calcium Gluconate Tablets

DEFINITION

Calcium Gluconate Effervescent Tablets contain Calcium Gluconate in a suitable effervescent basis.

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. Dissolve a quantity of the powdered tablets containing 1 g of Calcium Gluconate in 20 mL of hot <u>water</u>, cool and filter. To 0.5 mL of the filtrate add 0.05 mL of <u>iron(III) chloride solution R1</u>. An intense yellow colour is produced.
- B. To 5 mL of the filtrate obtained in test A 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 suitable quantity 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 reaction B characteristic of calcium salts, Appendix VI.
- D. The tablets effervesce on the addition of water.

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 C₁₂H₂₂CaO₁₄,H₂O.