Quality standards

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

Calcium Lactate Tablets

General Notices

DEFINITION

Calcium Lactate Tablets contain Calcium Lactate Pentahydrate or Calcium Lactate Trihydrate.

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

Content of calcium lactate, calculated as C₆H₁₀CaO₆,5H₂O

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. Triturate a quantity of the powdered tablets containing 0.3 g of Calcium Lactate Pentahydrate or its equivalent with 5 mL of <u>methanol</u> and filter. To 0.2 mL of the filtrate add 2 mL of <u>sulfuric acid</u>, heat at 85° for 2 minutes, cool and add 4 mg of <u>4-hydroxybiphenyl</u>. A violet-red colour is produced.
- B. The powdered tablets, when moistened with <u>hydrochloric acid</u> and introduced on a platinum wire into a flame, impart a brick red colour to the flame.

Disintegration

Maximum time, 30 minutes, Appendix XII A1.

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 0.3 g of Calcium Lactate Pentahydrate or its equivalent as completely as possible in 50 mL of <u>water</u> and titrate with 0.05M <u>disodium edetate VS</u> to within a few millilitres of the expected end point. Add 8 mL of 5M <u>sodium hydroxide</u> and 0.1 g of <u>solochrome dark blue mixture</u> and continue the titration until the colour changes from pink to full blue. Each mL of 0.05M <u>disodium edetate VS</u> is equivalent to 15.41 mg of $C_6H_{10}CaO_{6.5}H_{2}O$.

LABELLING

When the active ingredient is Calcium Lactate Trihydrate the quantity is stated in terms of the equivalent amount of Calcium Lactate Pentahydrate.