Quality standards

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

Calcium Borogluconate Injection

General Notices

DEFINITION

Calcium Borogluconate Injection is a sterile solution of Calcium Gluconate and Boric Acid in Water for Injections.

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

Content of calcium, Ca

95.0 to 105.0% of the stated amount.

Content of boric acid, H₃BO₃

Not more than 2.3 times the stated content of calcium.

IDENTIFICATION

- A. To 1 mL add sufficient <u>water</u> to produce a solution containing about 0.75% w/v of calcium and add 0.05 mL of <u>iron(III)</u> <u>chloride solution R1</u>. An intense yellow or yellowish green colour is produced.
- B. Yields the reactions characteristic of calcium salts, Appendix VI.
- C. To 1 mL add 0.15 mL of sulfuric acid and 5 mL of methanol and ignite. The mixture burns with a flame tinged with green.

Acidity

pH of the injection, diluted if necessary with <u>carbon dioxide-free water</u> to contain 1.5% w/v of calcium, 3.0 to 4.0, <u>Appendix V L</u>.

ASSAY

For calcium

Dilute a quantity containing the equivalent of 45 mg of calcium to about 50 mL with <u>water</u>. Titrate with 0.05M <u>disodium</u> <u>edetate VS</u> to within a few mL of the expected end point, add 4 mL of a 40% w/v solution of <u>sodium hydroxide</u> and 10 mg of <u>solochrome dark blue mixture</u> and continue the titration until the colour changes from pink to blue. Each mL of 0.05M <u>disodium edetate VS</u> is equivalent to 2.004 mg of Ca.

For boric acid

Dilute a quantity containing 0.1 g of Boric Acid to 50 mL with <u>water</u>, add 3 g of p-<u>mannitol</u> and titrate with <u>0.1_M sodium</u> <u>hydroxide VS</u> using <u>phenolphthalein solution R1</u> as indicator. Each mL of <u>0.1_M sodium hydroxide VS</u> is equivalent to

$\begin{array}{c} \text{https://nhathuocngocanh.com/bp} \\ \text{6.183 mg of H}_3\text{BO}_3. \end{array}$

STORAGE

Calcium Borogluconate Injection should be protected from light. It may be supplied in containers of *glass type III*, <u>Appendix XIX B</u>.

LABELLING

The strength is stated as the amount of calcium in a suitable dose-volume. The label also states the proportion of boric acid present.