Quality standards

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Calcium Chloride Injection

General Notices

DEFINITION

Calcium Chloride Injection is a sterile solution of Calcium Chloride Dihydrate in Water for Injections.

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

Content of calcium chloride dihydrate, CaCl₂,2H₂O

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. 1 mL yields reaction C characteristic of calcium salts, Appendix VI.
- B. Dilute 1 volume of the injection to 50 mL with <u>water</u>. The resulting solution yields reaction A characteristic of *chlorides*, <u>Appendix VI</u>.

TESTS

Acidity or alkalinity

pH 5.0 to 8.0, <u>Appendix V L</u>.

Colour of solution

The injection is not more intensely coloured than reference solution BY6, Appendix IV B, Method II.

ASSAY

Carry out the <u>complexometric titration of calcium</u>, <u>Appendix VIII D</u>. Use a volume of the injection containing about 0.3 g of Calcium Chloride Dihydrate. Each mL of 0.1_M <u>sodium edetate</u> is equivalent to 14.70 mg of CaCl₂,2H₂O.

LABELLING

The label states (1) the percentage w/v of Calcium Chloride Dihydrate; (2) the concentration of calcium ion as millimoles in a suitable volume; (3) the concentration of chloride ion as millimoles in a suitable volume; (4) that solutions containing visible solid particles must not be used.

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When calcium chloride intravenous infusion is prescribed or demanded, Calcium Chloride Injection shall be dispensed or supplied.