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Calcium Chloride Injection

» Calcium Chloride Injection is a sterile solution of Calcium Chloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass.

Labeling—The label states the total osmolar concentration in mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL.

Identification—It responds to the tests for [Calcium](#) and [Chloride \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.2 USP Endotoxin Unit per mg of calcium chloride.

pH (791): between 5.5 and 7.5 in the undiluted Injection, except where the concentration is greater than 1 in 20, in which case this range applies to the Injection diluted with water to yield a concentration of 1 in 20.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements for small-volume injections.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Transfer an accurately measured volume of Injection, equivalent to about 1 g of calcium chloride, to a 250-mL volumetric flask, add 5 mL of 3 N hydrochloric acid, dilute with water to volume, and mix. Pipet 50 mL of the resulting solution into a suitable container, add 100 mL of water, 15 mL of 1 N sodium hydroxide, and 300 mg of hydroxy naphthol blue, and titrate with 0.05 M edetate disodium VS until the solution is deep blue. Each mL of 0.05 M edetate disodium is equivalent to 7.351 mg of $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CALCIUM CHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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