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Calcium Gluconate Injection

DEFINITION

Calcium Gluconate Injection is a sterile solution of Calcium Gluconate in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of total calcium. The calcium is in the form of calcium gluconate, except that a small amount may be replaced with an equal amount of calcium in the form of Calcium Saccharate, or other suitable calcium salts, for the purpose of stabilization. It may contain sodium hydroxide or hydrochloric acid added for adjustment of the pH.

Injection intended for veterinary use only may be prepared from Calcium Gluconate solubilized with Boric Acid, or from Gluconolactone, Boric Acid, and Calcium Carbonate.

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Standard solution: 10 mg/mL of USP Potassium Gluconate RS

Sample solution: Dilute a volume of injection, if necessary, with water to obtain a concentration of 10 mg/mL of calcium gluconate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 µL

Developing solvent system: Alcohol, ethyl acetate, ammonium hydroxide, and water (50:10:10:30)

Spray reagent: Dissolve 2.5 g of ammonium molybdate in 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask. Add 1.0 g of ceric sulfate, swirl to dissolve, dilute with 2 N sulfuric acid to volume, and mix.

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry at 110° for 20 min. Allow to cool, and spray with the *Spray reagent*. Heat the plate at 110° for about 10 min.

Acceptance criteria: The principal spot of the *Sample solution* corresponds in color, size, and R_F value to that of the *Standard solution*.

• **B. Identification Tests—General, *Calcium* ⟨191⟩**

Sample solution: Dilute a volume of Injection with water to obtain a concentration of 20 mg/mL of calcium gluconate.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Sample: Accurately measured volume of Injection, equivalent to 46.5 mg of calcium

Blank: 150 mL of water containing 2 mL of 3 N hydrochloric acid

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Add 2 mL of 3 N hydrochloric acid to the *Sample*, and dilute with water to 150 mL. While stirring, add 20 mL of *Titrant* from the titration buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Perform a blank determination.

Calculate the percentage of the labeled amount of total calcium in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times M \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

M = *Titrant* molarity (mmol/mL)

F = equivalency factor, 40.08 mg/mmol

W = weight of calcium in the *Sample* (mg)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.17 USP Endotoxin Units/mg of calcium gluconate
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **pH ⟨791⟩:** 6.0–8.2; 2.5–4.5 where labeled as intended for veterinary use only and as containing boric acid
- **Injections and Implanted Drug Products ⟨1⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers, preferably of Type I glass.
- **Labeling:** Label the Injection to indicate its content, if any, of added calcium salts, calculated as percentage of calcium in the Injection. The label states the total osmolar concentration in mOsmol/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/mL. The labeling indicates that the Injection must be clear at the time of use, and that if crystallization has occurred, warming may redissolve the precipitate. Injection intended for veterinary use only is so labeled. If Injection contains boric acid, it is so labeled.
- **USP Reference Standards ⟨11⟩**
  USP Potassium Gluconate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CALCIUM GLUCONATE INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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