

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-C38EEEE0-A60C-49ED-A035-71FE02F58000_4_en-US
DOI: https://doi.org/10.31003/USPNF_M11610_04_01
DOI Ref: u0I57

© 2025 USPC
Do not distribute

Calcium Gluceptate Injection

» Calcium Gluceptate Injection is a sterile solution of Calcium Gluceptate in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of calcium (Ca).

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

USP REFERENCE STANDARDS (11).—
[USP Calcium Gluceptate RS](#)

Identification—

Change to read:

A: ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-May-2020) —Prepare the test specimen as follows. Transfer 5 mL of Injection to a separator, add 10 mL of chloroform, shake, and allow the layers to separate. Draw off and discard the chloroform layer, and repeat the extraction with a second 10-mL portion of chloroform. Drain the water layer into a small beaker, evaporate to dryness, and dry in vacuum at 60° for 16 hours.

B: A dilution of the Injection with water (1 in 5) responds to the tests for [Calcium \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85).—It contains not more than 0.32 USP Endotoxin Unit per mg of calcium gluceptate.

pH (791): between 5.6 and 7.0.

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—To an accurately measured volume of Injection, equivalent to about 45 mg of calcium, add 2 mL of 3 N hydrochloric acid and 148 mL of water. While stirring, preferably with a magnetic stirrer, add about 15 mL of 0.05 M edetate disodium VS from a 50-mL buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 2.004 mg of calcium (Ca).

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 27(6)

Current DocID: GUID-C38EEEE0-A60C-49ED-A035-71FE02F58000_4_en-US
DOI: https://doi.org/10.31003/USPNF_M11610_04_01
DOI ref: [u0I57](#)