

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-20C2AEE3-D830-49BC-8D07-8E8AC929BCDE_3_en-US
DOI: https://doi.org/10.31003/USPNF_M11860_03_01
DOI Ref: 9cbh9

© 2025 USPC
Do not distribute

Calcium Levulinate Injection

» Calcium Levulinate Injection is a sterile solution of Calcium Levulinate in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{10}H_{14}CaO_6 \cdot 2H_2O$.

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 *Identification* tests under [Calcium Levulinate](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 35.70 USP Endotoxin Units per mg of calcium levulinate.

pH (791): between 6.0 and 8.0.

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—Transfer an accurately measured volume of Injection, equivalent to about 600 mg of calcium levulinate, to a 400-mL beaker, add 2 mL of hydrochloric acid, and proceed as directed in the Assay under [Calcium Levulinate](#), beginning with “While stirring with a magnetic stirrer.” Each mL of 0.05 M edetate disodium is equivalent to 15.32 mg of $C_{10}H_{14}CaO_6 \cdot 2H_2O$.

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-20C2AEE3-D830-49BC-8D07-8E8AC929BCDE_3_en-US

Previous DocID: GUID-20C2AEE3-D830-49BC-8D07-8E8AC929BCDE_1_en-US

DOI: https://doi.org/10.31003/USPNF_M11860_03_01

DOI ref: [9cbh9](#)