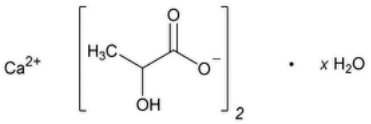
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Apr-2023
Document Type: USP Monographs
DocId: GUID-B3E2CE92-203D-4DFF-8A2E-2B08168B3113_5_en-US
DOI: https://doi.org/10.31003/USPNF_M11790_05_01
DOI Ref: 8n55g

Calcium Lactate

Change to read:



$C_6H_{10}CaO_6 \cdot 5H_2O$ 308.30
$C_6H_{10}CaO_6$ 218.22

Propanoic acid, 2-hydroxy-, calcium salt (2:1), hydrate;

Calcium lactate ▲▲ (ERR 1-Apr-2023) hydrate CAS RN®: 41372-22-9.

Calcium lactate ▲▲ (ERR 1-Apr-2023) pentahydrate CAS RN®: 5743-47-5.

Anhydrous CAS RN®: 814-80-2; UNII: 2URQ2N32W3.

DEFINITION

Calcium Lactate contains NLT 98.0% and NMT 101.0% of calcium lactate ($C_6H_{10}CaO_6$), calculated on the dried basis.

IDENTIFICATION

- **A. Identification Tests—General, *Calcium* ⟨191⟩:** Meets the requirements
- **B. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

ASSAY

- **Procedure**

Sample: Weighed portion of Calcium Lactate equivalent to 350 mg of $C_6H_{10}CaO_6$

Blank: 150 mL of water and 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: Dissolve the *Sample* in a mixture of water and 3 N hydrochloric acid (150:2). While stirring with a magnetic stirrer, add 30 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 the *Blank* determination.

Calculate the percentage of calcium lactate ($C_6H_{10}CaO_6$) 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 (mM/mL)

F = equivalency factor, 218.2 mg/mM

W = *Sample* weight (mg)

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

- **Limit of Magnesium and Alkali Salts**

Sample: 1.0 g Calcium Lactate

Analysis: Mix the *Sample* with 40 mL of water, carefully add 1 mL of hydrochloric acid, and heat the solution to boiling. Rapidly add 40 mL of oxalic acid TS, and stir vigorously until precipitation is well established. Add immediately to the warm mixture 2 drops of methyl red TS and then 6 N ammonium hydroxide, dropwise, until the mixture is just alkaline. Cool to room temperature, transfer to a 100-mL graduated

cylinder, dilute with water to 100 mL, mix, and allow to stand for 4 h or overnight. Filter, and to 50 mL of the clear filtrate in a platinum dish add 0.5 mL of sulfuric acid. Evaporate the mixture on a steam bath to a small volume. Carefully heat over a free flame to dryness, and continue heating to complete decomposition and volatilization of ammonium salts. Finally, ignite the residue to constant weight.

Acceptance criteria: NMT 1.0%: The weight of the residue does not exceed 5.0 mg.

• **Volatile Fatty Acid**

Sample solution: Stir 500 mg of Calcium Lactate with 1 mL of sulfuric acid, and warm.

Acceptance criteria: The mixture does not emit an odor of volatile fatty acid.

SPECIFIC TESTS

• **Acidity**

Sample solution: 50 mg/mL

Analysis: Titrate 20 mL of *Sample solution* with 0.10 N sodium hydroxide, using phenolphthalein TS as the indicator.

Acceptance criteria: NMT 0.50 mL is required for neutralization, equivalent to NMT 0.45% as lactic acid.

• **Loss on Drying ⟨731⟩**

Sample: 1–2 g

Analysis: Distribute the *Sample* evenly in a suitable weighing dish to a depth of NMT 3 mm, and dry at 120° for 4 h.

Acceptance criteria: See *Table 1*.

Table 1

Form	Loss on Drying (%)
Pentahydrate	22.0–27.0
Trihydrate	15.0–20.0
Monohydrate	5.0–8.0
Anhydrous	NMT 3.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** The label indicates whether it is the dried form or is hydrous; if the latter, the label indicates the degree of hydration. Where the quantity of Calcium Lactate is indicated in the labeling of any solution containing Calcium Lactate, this shall be understood to be in terms of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$).

• **USP Reference Standards ⟨11⟩**

USP Calcium Lactate RS

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

Topic/Question	Contact	Expert Committee
CALCIUM LACTATE	Nagaphani Batchu Senior Scientist I, Documentary Standards	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 31(6)

Current DocID: GUID-B3E2CE92-203D-4DFF-8A2E-2B08168B3113_5_en-US

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