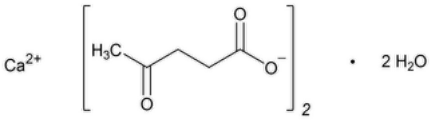
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: USP Monographs
DocId: GUID-4D6F56AE-C8D4-40B7-856D-C9CDC4565AF6_3_en-US
DOI: https://doi.org/10.31003/USPNF_M11850_03_01
DOI Ref: m71om

Calcium Levulinate



$C_{10}H_{14}CaO_6 \cdot 2H_2O$ 306.32
$C_{10}H_{14}CaO_6$ 270.30
Pentanoic acid, 4-oxo-, calcium salt (2:1), dihydrate;
Calcium levulinate (1:2) dihydrate CAS RN®: 5743-49-7; UNII: T6133SO781.
Anhydrous CAS RN®: 591-64-0; UNII: LLQ966USIL.

DEFINITION

Calcium Levulinate contains NLT 97.5% and NMT 100.5% of calcium levulinate ($C_{10}H_{14}CaO_6$), calculated on the dried basis.

IDENTIFICATION

- **A. Identification Tests—General, *Calcium*⟨191⟩:** A 100 mg/mL solution meets the requirements.
- **B.**

Sample solution: 0.5 g in 5 mL of water

Analysis: To the *Sample solution* add 5 mL of 1 N sodium hydroxide, and filter. To the filtrate add 5 mL of iodine TS.

Acceptance criteria: A precipitate of iodoform is produced.

ASSAY

- **Procedure**

Sample: 600 mg of Calcium Levulinate

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: Dissolve the *Sample* in 150 mL of water containing 2 mL of 3 N hydrochloric acid. 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 levulinate ($C_{10}H_{14}CaO_6$) 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, 270.3 mg/mM

W = *Sample* weight (mg)

Acceptance criteria: 97.5%–100.5% on the dried basis

IMPURITIES

- **Chloride and Sulfate, *Chloride*⟨221⟩**

Standard: 1.0 mL of 0.020 N hydrochloric acid

Sample: 1.0 g

Acceptance criteria: NMT 0.07%

- **Chloride and Sulfate, *Sulfate*⟨221⟩**

Standard: 1.0 mL of 0.020 N sulfuric acid

Sample: 2.0 g

Acceptance criteria: NMT 0.05%

- **Reducing Sugars**

Sample: 0.50 g

Analysis: Dissolve the *Sample* in 10 mL of water, add 2 mL of 3 N hydrochloric acid, boil for about 2 min, and cool. Add 5 mL of sodium carbonate TS, allow to stand for 5 min, dilute with water to 20 mL, and filter. Add 5 mL of the clear filtrate to 2 mL of alkaline cupric tartrate TS, and boil for 1 min.

Acceptance criteria: No red precipitate is formed immediately.

SPECIFIC TESTS

- **Melting Range or Temperature, *Class I*⟨741⟩:** 119°–125°
- **pH** ⟨791⟩

Sample solution: 100 mg/mL

Acceptance criteria: 7.0–8.5

- **Loss on Drying** ⟨731⟩**:** Dry a sample at a pressure not exceeding 5 mm of mercury at 60° for 5 h: it loses 10.5%–12.0% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.

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

Topic/Question	Contact	Expert Committee
CALCIUM LEVULINATE	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 27(6)

Current DocID: GUID-4D6F56AE-C8D4-40B7-856D-C9CDC4565AF6_3_en-US
Previous DocID: GUID-4D6F56AE-C8D4-40B7-856D-C9CDC4565AF6_1_en-US
DOI: https://doi.org/10.31003/USPNF_M11850_03_01
DOI ref: m71om