

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-28239439-DA55-4FB6-937E-0046C8C1CAD9_4_en-US
DOI: https://doi.org/10.31003/USPNF_M11970_04_01
DOI Ref: yy397

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Racemic Calcium Pantothenate

$C_{18}H_{32}CaN_2O_{10}$ 476.53
 β -Alanine, *N*-(2,4-dihydroxy-3,3-dimethyl-1-oxobutyl)-, calcium salt (2:1), ($\pm$)-;
Calcium DL-pantothenate (1:2) CAS RN®: 6381-63-1; UNII: 2KC899R47Q.

DEFINITION

Racemic Calcium Pantothenate is a mixture of the calcium salts of the dextrorotatory and levorotatory isomers of pantothenic acid. It contains NLT 5.7% and NMT 6.0% of nitrogen (N), and NLT 8.2% and NMT 8.6% of calcium (Ca), both calculated on the dried basis.
[NOTE—The physiological activity of Racemic Calcium Pantothenate is approximately one-half that of Calcium Pantothenate.]

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL, Calcium\(191\)](#): A 50-mg/mL solution meets the requirements.

COMPOSITION

- [NITROGEN DETERMINATION, Method I\(461\)](#)

Sample: 500 mg
Analysis: Proceed as directed in the chapter.
Acceptance criteria: 5.7%–6.0% on the dried basis

• **CONTENT OF CALCIUM**

Sample: 800 mg
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. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and titrate with the *Titrant* to a distinct blue endpoint. Perform the *Blank* determination.
Calculate the percentage of calcium (Ca) 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 = actual molarity of the *Titrant* (mM/mL)
 F = equivalency factor, 40.08 mg/mM
 W = *Sample* weight (mg)

Acceptance criteria: 8.2%–8.6% on the dried basis

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation\(781S\)](#)

Test solution: 50 mg/mL in water
Acceptance criteria: -0.05° to $+0.05^\circ$

• **ALKALINITY**

Sample: 1.0 g
Analysis: Dissolve the *Sample* in 15 mL of carbon dioxide-free water in a small flask. As soon as the solution is complete, add 1.6 mL of 0.10 N hydrochloric acid, and then add 0.05 mL of phenolphthalein TS.
Acceptance criteria: No pink color is produced within 5 s.

- **Loss on Drying (731):** Dry a sample at 105° for 3 h: it loses NMT 5.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Label preparations containing it in terms of the equivalent amount of dextrorotatory calcium pantothenate.
- **USP REFERENCE STANDARDS (11):**
[USP Calcium Pantothenate RS](#)

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

Topic/Question	Contact	Expert Committee
RACEMIC CALCIUM PANTOTHENATE	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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