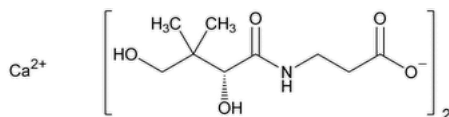


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Dec-2023
 Document Type: USP Monographs
 DocId: GUID-2ABC90FA-F72D-4CD8-A2CF-90C09578D047_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M11910_05_01
 DOI Ref: l6vo3

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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), (*R*)-;
 Calcium *D*-pantothenate (1:2) CAS RN®: 137-08-6; UNII: 568ET80C3D.

DEFINITION

Calcium Pantothenate is the calcium salt of the dextrorotatory isomer of pantothenic acid. It contains NLT 98.0% and NMT 102.0% of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$), calculated on the dried basis.

IDENTIFICATION

- A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197K
- B. IDENTIFICATION TESTS—GENERAL** (191), *Chemical Identification Tests, Calcium*
Sample solution: 50 mg/mL
Acceptance criteria: Meets the requirements
- C. OPTICAL ROTATION** (781S), *Procedures, Specific Rotation*
Sample solution: 50 mg/mL in [water](#)
Acceptance criteria: +25.0° to +27.5°

ASSAY

Change to read:

PROCEDURE

▲ **Mobile phase:** Dissolve 1.56 g of [monobasic sodium phosphate](#) in 900 mL of [water](#), and adjust the pH to 2.5 with concentrated [ortho-phosphoric acid](#). Add 10 mL of [acetonitrile](#) and dilute with [water](#) to 1000 mL.

System suitability solution: 0.04 mg/mL of [USP Calcium Pantothenate RS](#) and 0.1 mg/mL of [USP Pantolactone RS](#) in [water](#)

Standard solution: 0.5 mg/mL of [USP Calcium Pantothenate RS](#) in [water](#)

Sample solution: 0.5 mg/mL of Calcium Pantothenate in [water](#)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 200 nm

Column: 3.0-mm × 15-cm; 3.5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1.2 mL/min

Injection volume: 5 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for pantolactone and pantothenic acid are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between pantolactone and pantothenic acid peaks, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$) in the portion of Calcium Pantothenate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of pantothenic acid from the *Sample solution*

r_s = peak area of pantothenic acid from the *Standard solution*

C_s = concentration of [USP Calcium Pantothenate RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Calcium Pantothenate in the *Sample solution* (mg/mL)

▲ (USP 1-Dec-2023)

Acceptance criteria: 98.0%–102.0% on the dried basis

OTHER COMPONENTS

• CONTENT OF CALCIUM

Sample: 800 mg of Calcium Pantothenate

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 *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* (mmol/mL)

F = equivalency factor, 40.08 mg/mmol

W = *Sample* weight (mg)

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

Add the following:

▲ IMPURITIES

• BETA ALANINE AND OTHER AMINOCARBOXYLIC ACID IMPURITIES

Sample: 8.000 g of Calcium Pantothenate

Blank: 100 mL of [water](#) and 25 mL of formaldehyde solution

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [0.1 N sodium hydroxide VS](#)

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* in 40 mL of [water](#) and dilute with the same solvent to 100 mL. Add 25 mL of [formaldehyde solution](#) and titrate with *Titrant*. Perform the blank determination.

Calculate the percentage of β-alanine in the *Sample* taken:

$$\text{Result} = [(V_s - V_b) \times N \times F / W] \times 100$$

V_s = *Titrant* volume consumed by the *Sample* (mL)

V_b = *Titrant* volume consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 89.09 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: NMT 0.5%

• OTHER RELATED SUBSTANCES

Mobile phase and **Chromatographic system:** Proceed as directed in the Assay.

Standard solution: 0.004 mg/mL of [USP Calcium Pantothenate RS](#), 0.04 mg/mL of [USP Sodium D-Pantoate RS](#), and 0.02 mg/mL of [USP Pantolactone RS](#) in [water](#)