Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2013
Document Type: USP Monographs
DocId: GUID-7BC27C17-3D76-4864-A88B-B1BAE5D5FBA4_1_en-US
DOI: https://doi.org/10.31003/USPNF_M11940_01_01
DOI Ref: 66vui

Calcium Pantothenate Tablets

DEFINITION

Calcium Pantothenate Tablets contain NLT 95.0% and NMT 115.0% of the labeled amount of the dextrorotatory isomer of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$).

IDENTIFICATION

- **A. Identification Tests—General, *Calcium* ⟨191⟩**

  Sample solution: Digest a quantity of powdered Tablets, equivalent to 150 mg of calcium pantothenate, with 15 mL of 1 N sodium hydroxide, and filter.

  Acceptance criteria: Meet the requirements

- **B.**

  Sample solution: 5 mL of the filtrate obtained in *Identification* test *A*

  Analysis: Add 5 mL of 1 N hydrochloric acid and 2 drops of ferric chloride TS to the *Sample solution*.

  Acceptance criteria: A strong yellow color is produced.

ASSAY

- **Calcium Pantothenate**

  Buffer solution: Dissolve 10.0 g of monobasic potassium phosphate in 2000 mL of water, and adjust with phosphoric acid to a pH of 3.5.

  Mobile phase: Methanol and *Buffer solution* (1:9)

  System suitability solution: 0.5 mg/mL of USP Calcium Pantothenate RS and 0.1 mg/mL of USP Racemic Panthenol RS in water

  Standard solution: 0.5 mg/mL of USP Calcium Pantothenate RS in water

  Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 50 mg of calcium pantothenate, to a 100-mL volumetric flask. Add 5 mL of methanol, and swirl the flask to disperse. Dilute with water to volume, mix, and filter.

  Chromatographic system

  (See *Chromatography ⟨621⟩, System Suitability*.)

  Mode: LC

  Detector: UV 205 nm

  Column: 4.6-mm × 25-cm; 5-µm packing L1

  Column temperature: 50°

  Flow rate: 2 mL/min

  Injection volume: 25 µL

  System suitability

  Sample: *System suitability solution*

  [Note—The relative retention times for pantothenate and panthenol are 1.0 and 1.1, respectively.]

  Suitability requirements

  Resolution: NLT 1.5 between pantothenate and panthenol

  Relative standard deviation: NMT 2.0%

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Measure the peak areas for calcium pantothenate.

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

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

  r_U = peak area from the *Sample solution*

  r_S = peak area from the *Standard solution*

  C_S = concentration of USP Calcium Pantothenate RS in the *Standard solution* (mg/mL)

  C_U = nominal concentration of calcium pantothenate in the *Sample solution* (mg/mL)

  Acceptance criteria: 95.0%–115.0%

OTHER COMPONENTS

• **Content of Calcium**

Sample: A portion of the powder from NLT 20 finely powdered Tablets, equivalent to 500 mg of calcium pantothenate

Blank: Proceed as directed in the *Analysis*, without the *Sample*.

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Indicator: Hydroxy naphthol blue, 300 mg

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a suitable crucible. Ignite, gently at first, until free from carbon. Cool the crucible. Add 10 mL of water, and dissolve the residue by adding sufficient 3 N hydrochloric acid, dropwise, to completely dissolve. Transfer the solution to a suitable container, and dilute with water to 150 mL. Add 15 mL of 1 N sodium hydroxide, then add the *Indicator*. Titrate with *Titrant* to a distinct blue endpoint. Perform a blank determination.

Calculate the percentage of calcium in the content of calcium pantothenate, as determined by the *Assay*, in the portion of Tablets 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 = weight of calcium pantothenate in the *Sample* taken, as determined by the *Assay* (mg)

Acceptance criteria: 7.9%–9.7% of the weight of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$) in the Tablets, as determined by the *Assay*

PERFORMANCE TESTS

• **Dissolution,** *Procedure for a Pooled Sample ⟨711⟩*

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase: Phosphoric acid and water (1:1000)

Standard solution: A known concentration of USP Calcium Pantothenate RS in *Medium*

Sample solution: A filtered portion of the solution under test, suitably diluted with *Medium* if necessary, having a concentration of $C_{18}H_{32}CaN_2O_{10}$ similar to that of the *Standard solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 3.9-mm × 15-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$) dissolved:

$$\text{Result} = (r_U/r_S) \times [C_S \times D \times (V/L)] \times 100$$

r_U = peak area of calcium pantothenate from the *Sample solution*

r_S = peak area of calcium pantothenate from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Label the Tablets to indicate the content of dextrorotatory calcium pantothenate.

• **USP Reference Standards ⟨11⟩**

USP Calcium Pantothenate RS

USP Racemic Panthenol RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(1)

Current DocID: GUID-7BC27C17-3D76-4864-A88B-B1BAE5D5FBA4_1_en-US

DOI: https://doi.org/10.31003/USPNF_M11940_01_01

DOI ref: 66vui