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Calcium Acetate Capsules

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DEFINITION

Calcium Acetate Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of calcium acetate ($C_4H_6CaO_4$).

IDENTIFICATION

- **A.** The retention time of the calcium peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Acetate](#)
Sample solution: 67 mg/mL of calcium acetate from Capsule contents
Acceptance criteria: Meet the requirements for test B

ASSAY

PROCEDURE

Solution A: 0.75 mM [dipicolinic acid](#) and 1.7 mM [nitric acid](#) in [water](#). [NOTE—Warm [water](#) may be required to dissolve [dipicolinic acid](#).]

Mobile phase: [Acetone](#) and *Solution A* (10:90). Pass through a suitable filter of 0.2-μm pore size.

Standard solution: 0.08 mg/mL of [USP Calcium Acetate RS](#) in [water](#)

Sample stock solution: Nominally 6.7 mg/mL of calcium acetate prepared as follows. Transfer an appropriate portion of the contents of NLT 20 Capsules to a suitable volumetric flask. Add [water](#) to about 40% of the final volume of the flask and sonicate for 20 min with intermittent shaking. Dilute with [water](#) to volume. Pass through a suitable filter of 0.45-μm pore size.

Sample solution: Nominally 0.08 mg/mL of calcium acetate in [water](#) from the *Sample stock solution*

Chromatographic system

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

Mode: Ion chromatography

Detector: Conductivity

Column: 4.0-mm × 15-cm; 5-μm packing [L76](#)

Column temperature: 35°

Flow rate: 0.9 mL/min

Injection volume: 10 μL

Run time: NLT 1.5 times the retention time of the calcium peak

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of calcium acetate ($C_4H_6CaO_4$) in the portion of Capsules taken:

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

r_U = peak response of calcium from the *Sample solution*

r_S = peak response of calcium from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Test 1

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm, with sinkers

Time: 10 min

Solution A, Mobile phase, Standard solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Dilute with *Medium* to a concentration similar to the *Standard solution*, if necessary.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of calcium acetate ($C_4H_6CaO_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times (1/L) \times 100$$

r_U = peak response of calcium from the *Sample solution*

r_S = peak response of calcium from the *Standard solution*

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

V = volume of *Medium*, 900 mL

D = dilution factor of the *Sample solution*, if needed

L = label claim (mg/Capsule)

Tolerances: NLT 80% (Q) of the labeled amount of calcium acetate ($C_4H_6CaO_4$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 1: 100 rpm

Time: 15 min

Blank: 0.2% (v/v) [nitric acid](#)

Standard solution A: 4.0 µg/mL of calcium¹ in the *Blank*

Standard solution B: 5.0 µg/mL of calcium¹ in the *Blank*

Standard solution C: 6.0 µg/mL of calcium¹ in the *Blank*

Standard solution D: 7.0 µg/mL of calcium¹ in the *Blank*

Standard solution E: 8.0 µg/mL of calcium¹ in the *Blank*

Sample solution: Pass a portion of the solution under test through a suitable filter of 1.0-µm pore size. Dilute with *Blank* to a concentration similar to *Standard solution C*, if necessary.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrometry

Analytical wavelength: 422.8 nm

Lamp: Calcium hollow-cathode

Flame: Air–acetylene oxidizing flame

System suitability

Samples: *Blank*, *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, and *Standard solution E*

Suitability requirements

Correlation coefficient: NLT 0.995, from the linear regression in the *Analysis*

Drift: Within ±2%, *Standard solution D*. (See [Atomic Absorption Spectroscopy \(852\), Procedure, Analysis](#).)

Analysis

Samples: *Blank*, *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, *Standard solution E*, and *Sample solution*

Use the *Blank* to set the instrument to zero. Concomitantly determine the responses for *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, and *Standard solution E*. Construct a linear calibration curve by plotting the absorbance values of *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, and *Standard solution E* versus their corresponding concentrations, in µg/mL. From the linear calibration curve, determine the concentration (C), in µg/mL, for calcium in the *Sample solution*.

Calculate the percentage of the labeled amount of calcium acetate ($C_4H_6CaO_4$) dissolved:

$$\text{Result} = C \times V \times F \times D \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

C = concentration of calcium in the *Sample solution* (µg/mL)