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Calcium Acetate Tablets

DEFINITION

Calcium Acetate Tablets 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: 100 mg/mL of calcium acetate from powdered Tablets

Acceptance criteria: Meet the requirements

ASSAY

PROCEDURE

Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.

Mobile phase: 34 mM [methanesulfonic acid](#). [NOTE—It is recommended to use suitable cation trapping techniques to ensure the *Mobile phase* is free of all cationic impurities.]

Diluent: 0.02 N [hydrochloric acid](#)

System suitability solution: 100 µg/mL of [USP Calcium Acetate RS](#) and 2 µg/mL of magnesium¹ in *Diluent*

Standard solution: 100 µg/mL of [USP Calcium Acetate RS](#) in *Diluent*

Sample stock solution: Nominally 2.5 mg/mL of calcium acetate, prepared as follows. Finely powder NLT 30 Tablets and transfer an appropriate portion of the powder to a suitable container. Add 6 N [hydrochloric acid](#) to about 10% of the final volume of the flask. Heat to boiling with constant swirling for 10 min. Allow to cool to room temperature. Transfer the solution quantitatively to a suitable volumetric flask containing 10% of the flask volume of [water](#). Dilute with [water](#) to volume. Pass through a suitable filter of 0.45-µm pore size.

Sample solution: Nominally 100 µg/mL of calcium acetate in [water](#), from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 5-mm × 5-cm; 5.5-µm packing [L84](#)

Analytical: 5-mm × 25-cm; 5.5-µm packing [L84](#)

Column temperature: 50°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: NLT 2.5 times the retention time of calcium

System suitability

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

[NOTE—The relative retention times for the magnesium and calcium ions are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the magnesium and calcium ions, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

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 Tablets 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* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: Calcium at a known concentration in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium* to a concentration that is similar to the *Standard solution*, if necessary.

Instrumental conditions

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

Mode: Atomic absorption spectrometry

Analytical wavelength: 422.8 nm

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

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

Change to read:

• LIMIT OF ALUMINUM

Buffer: Dissolve 50 g of [ammonium acetate](#) in 150 mL of [water](#), adjust with [glacial acetic acid](#) to a pH of 6.0, and dilute with [water](#) to 250 mL.

Aluminum standard solution: 1.0 µg/mL of aluminum. Prepare as directed in [▲Aluminum \(206\), Procedure 1▲](#) (CN 1-Jun-2023) ·

Standard solution: Prepare a solution containing 2.0 mL of *Aluminum standard solution*, 5 mL of *Buffer*, and 48 mL of [water](#), and extract this solution with successive portions of 10, 10, and 5 mL of 0.5% [8-hydroxyquinoline](#) in [chloroform](#). Combine the chloroform extracts in a 50-mL volumetric flask, and dilute the combined extracts with [chloroform](#) to volume.

Sample solution: Dissolve a portion of powdered Tablets (NLT 10) equivalent to 1.0 g of calcium acetate in 50 mL of [water](#), and add 5 mL of *Buffer*. Extract this solution with successive portions of 10, 10, and 5 mL of 0.5% [8-hydroxyquinoline](#) in [chloroform](#). Combine the chloroform extracts in a 50-mL volumetric flask, and dilute the combined extracts with [chloroform](#) to volume.

Blank solution: Prepare a solution containing 50 mL of [water](#) and 5 mL of *Buffer*. Extract this solution with successive portions of 10, 10, and 5 mL of 0.5% [8-hydroxyquinoline](#) in [chloroform](#). Combine the chloroform extracts in a 50-mL volumetric flask, and dilute the combined extracts with [chloroform](#) to volume.

Instrumental conditions

(See [Fluorescence Spectroscopy \(853\)](#).)

Mode: Fluorescence

Excitation wavelength: 392 nm

Emission wavelength: 518 nm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank solution*

Use the *Blank solution* to zero the instrument.

Acceptance criteria: The fluorescence of the *Sample solution* does not exceed that of the *Standard solution* (NMT 2 ppm).

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers and store at controlled room temperature.

• **USP REFERENCE STANDARDS (11)**

[USP Calcium Acetate RS](#)

¹ From commercially available National Institute of Standards and Technology (NIST)-traceable standard solution for magnesium.

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

Topic/Question	Contact	Expert Committee
CALCIUM ACETATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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