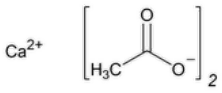
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
DocId: GUID-D4C8EE04-D86B-4067-A40F-B09840F5B7E6_5_en-US
DOI: https://doi.org/10.31003/USPNF_M11400_05_01
DOI Ref: 2h91h

Calcium Acetate



$C_4H_6CaO_4$ 158.17

Acetic acid, calcium salt;

Calcium acetate CAS RN®: 62-54-4; UNII: Y882YXF34X.

DEFINITION

Calcium Acetate contains NLT 99.0% and NMT 100.5% of calcium acetate ($C_4H_6CaO_4$), calculated on the anhydrous basis.

IDENTIFICATION

• **A. Identification Tests—General, *Calcium*⟨191⟩and*Acetate*⟨191⟩**

Sample solution: 50 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Sample: 300 mg

Analysis: Dissolve the *Sample* in 150 mL of water containing 2 mL of 3 N hydrochloric acid. While stirring, preferably with a magnetic stirrer, add about 30 mL of 0.05 M edetate disodium VS from a 50-mL buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 7.909 mg of calcium acetate ($C_4H_6CaO_4$).

Acceptance criteria: 99.0%–100.5% on the anhydrous basis

IMPURITIES

Change to read:

• **▲Arsenic ⟨211⟩, *Procedures, Procedure 1*▲** (CN 1-Jun-2023) **:** NMT 3 ppm

• **Chloride and Sulfate, *Chloride*⟨221⟩**

Standard: 0.70 mL of 0.020 N hydrochloric acid

Sample: 1.0 g

Acceptance criteria: 0.05%

• **Chloride and Sulfate, *Sulfate*⟨221⟩**

Standard: 0.15 mL of 0.020 N sulfuric acid

Sample: 0.25 g

Acceptance criteria: 0.06%

Change to read:

• **▲Lead ⟨251⟩, *Procedures, Procedure 1*▲** (CN 1-Jun-2023) **:** NMT 10 ppm

Change to read:

• **Limit of Aluminum**

[Note—Use where it is labeled as intended for parenteral use or for use in hemodialysis or peritoneal dialysis.]

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 for *Standard Preparations* in ▲*Aluminum ⟨206⟩, Procedures, 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. Dilute the combined extracts with chloroform to volume.

Sample solution: Dissolve 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. 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. 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: 2 ppm; the fluorescence of the *Sample solution* is NMT that of the *Standard solution*.

- **Limit of Barium**

[Note—Use where it is labeled as intended for use in hemodialysis or peritoneal dialysis.]

Barium chloride solution: 500 µg/mL of barium in water from anhydrous barium chloride

Buffer: Ammonium sulfate solution (1 in 10)

Standard solution: To a tube add 1 g of ammonium acetate, 2 mL of 1 N hydrochloric acid, 3.0 mL of *Barium chloride solution*, and sufficient water to bring the volume to 40 mL.

Sample stock solution: 250 mg/mL of Calcium Acetate and 25 mg/mL of ammonium acetate in 1 N hydrochloric acid. The pH of this solution is 4.5–5.5. Filter, and cover the solution.

Sample solutions: To four separate tubes add 1.0, 1.5, 2.0, and 2.5 mL of *Barium chloride solution*. To each tube add a sufficient volume of the *Sample stock solution* to bring the volume to 40 mL.

Analysis: To the *Sample solutions* and the *Standard solution* add, with brisk stirring, 3.0 mL of *Buffer*, and allow to stand for 20 min.

Acceptance criteria: The *Sample solutions* containing 1.0 and 1.5 mL of *Barium chloride solution* remain clear or are only faintly turbid. The *Sample solution* containing 2.0 mL of *Barium chloride solution* is not more turbid than the *Standard solution*.

- **Limit of Fluoride**

[Note—Prepare and store all solutions in plastic containers.]

Buffer: 294 mg/mL of sodium citrate dihydrate in water

Standard stock solution: 1.11 mg/mL of USP Sodium Fluoride RS in water

Standard solution: Combine 20.0 mL of *Standard stock solution* with 50.0 mL of *Buffer*, and dilute with water to 100.0 mL. Equivalent to 100 µg/mL of fluoride

Sample solution: Transfer 2.0 g of Calcium Acetate to a beaker containing a plastic-coated stirring bar. Add 20.0 mL of water and 2.0 mL of hydrochloric acid, and stir until dissolved. Add 50.0 mL of *Buffer* and sufficient water to make 100 mL.

Electrode system: Use a fluoride-specific, ion-indicating electrode and a silver–silver chloride reference electrode connected to a pH meter capable of measuring potentials with a minimum reproducibility of ±0.2 mV (see *pH ⟨791⟩*).

Analysis

Samples: *Standard solution* and *Sample solution*

Transfer 50.0 mL of *Buffer* and 2.0 mL of hydrochloric acid to a beaker, and add water to make 100 mL. Add a plastic-coated stirring bar, insert the electrodes into the solution, stir for 15 min, and read the potential, in mV. Continue stirring, and at 5-min intervals add 100, 100, 300, and 500 µL of the *Standard solution*, reading the potential 5 min after each addition. Plot the logarithms of the cumulative fluoride ion concentrations (0.1, 0.2, 0.5, and 1.0 µg/mL) versus potential, in mV.

Rinse and dry the electrodes, insert them into the *Sample solution*, stir for 5 min, and read the potential, in mV. From the measured potential and the standard response line determine the concentration, *C*, in µg/mL, of fluoride ion in the *Sample solution*.

Calculate the amount of fluoride (ppm) in the sample taken by multiplying *C* by 50.

Acceptance criteria: 50 ppm

- **Limit of Magnesium**

[Note—Use where it is labeled as intended for use in hemodialysis or peritoneal dialysis. The *Standard solution* and the *Sample solutions* may be modified, if necessary, to obtain solutions of suitable concentrations, adaptable to the linear or working range of the instrument.]

Standard stock solution: 1000 µg/mL of magnesium in 1 N nitric acid from magnesium oxide

Standard solution: 5.0 µg/mL of magnesium from the *Standard stock solution*

Sample solution: 2 mg/mL of Calcium Acetate

Linearity solution A: Dilute 20.0 mL of the *Sample solution* with water to 25.0 mL (0 µg/mL of magnesium).

Linearity solution B: Dilute 2.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (0.4 µg/mL of magnesium).

Linearity solution C: Dilute 4.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (0.8 µg/mL of magnesium).

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 285.2 nm

Flame: Air–acetylene

Lamp: Magnesium hollow-cathode

Blank: Water

Analysis

Samples: *Linearity solutions A, B*, and *C*

Plot the absorbances of the *Linearity solutions* versus their content of magnesium (0, 0.4, and 0.8 µg/mL), draw the straight line best fitting the three points, and extrapolate the line until it intercepts the concentration axis. From the intercept determine the amount, in µg/mL, of magnesium in the *Sample solution*.

Calculate the percentage of magnesium in the sample by multiplying this value by 0.0625.

Acceptance criteria: NMT 0.05%

• **Limit of Nitrate**

Sample solution: 100 mg/mL of Calcium Acetate in water

Analysis: To 10 mL of the *Sample solution* add 5 mg of sodium chloride, 0.05 mL of indigo carmine TS, and, with stirring, 10 mL of nitrogen-free sulfuric acid.

Acceptance criteria: The blue color persists for NLT 10 min.

• **Limit of Potassium**

[Note—Use where it is labeled as intended for use in hemodialysis or peritoneal dialysis. The *Standard solution* and *Sample solutions* may be modified, if necessary, to obtain solutions of suitable concentrations, adaptable to the linear or working range of the instrument.]

Standard stock solution: 23.84 mg/mL of potassium chloride, using potassium chloride previously dried at 105° for 2 h, equivalent to 12.5 mg/mL of potassium

Standard solution: 31.25 µg/mL of potassium from the *Standard stock solution*

Sample solution: 12.5 mg/mL of Calcium Acetate

Linearity solution A: Dilute 20.0 mL of the *Sample solution* with water to 25.0 mL (0 µg/mL of potassium).

Linearity solution B: Dilute 2.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (2.5 µg/mL of potassium).

Linearity solution C: Dilute 4.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (5.0 µg/mL of potassium).

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 766.7 nm

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Blank: Water

Analysis

Samples: *Linearity solutions A, B*, and *C*

Plot the absorbances of the *Linearity solutions* versus their content of potassium (0, 2.5, and 5.0 µg/mL), draw the straight line best fitting the three points, and extrapolate the line until it intercepts the concentration axis. From the intercept determine the amount, in µg/mL, of potassium in the *Sample solution*.

Calculate the percentage of potassium in the sample by multiplying this value by 0.01.

Acceptance criteria: NMT 0.05%

• **Limit of Sodium**

[Note—Use where it is labeled as intended for use in hemodialysis or peritoneal dialysis. The *Standard solution* and the *Sample solutions* may be modified, if necessary, to obtain solutions of suitable concentrations, adaptable to the linear or working range of the instrument.]

Standard stock solution: 25.42 mg/mL of sodium chloride, using sodium chloride previously dried at 105° for 2 h, equivalent to 10.0 mg/mL of sodium

Standard solution: 250 µg/mL of sodium from the *Standard stock solution*

Sample solution: 10 mg/mL of Calcium Acetate

Linearity solution A: Dilute 20.0 mL of the *Sample solution* with water to 25.0 mL (0 µg/mL of sodium).

Linearity solution B: Dilute 2.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (20 µg/mL of sodium).

Linearity solution C: Dilute 4.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (40 µg/mL of sodium).

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 589.0 nm

Lamp: Sodium hollow-cathode

Flame: Air–acetylene

Blank: Water

Analysis

Samples: *Linearity solutions A, B*, and *C*

Plot the absorbances of the *Linearity solutions* versus their content of sodium (0, 20, and 40 µg/mL), draw the straight line best fitting the three points, and extrapolate the line until it intercepts the concentration axis. From the intercept determine the amount, in µg/mL, of sodium in the *Sample solution*.

Calculate the percentage of sodium in the sample by multiplying this value by 0.0125.

Acceptance criteria: NMT 0.5%

• **Limit of Strontium**

[Note—Use where it is labeled as intended for use in hemodialysis or peritoneal dialysis. The *Standard solution* and *Sample solutions* may be modified, if necessary, to obtain solutions of suitable concentrations, adaptable to the linear or working range of the instrument.]

Standard stock solution: 2.45 mg/mL of strontium acetate in water, equivalent to 1000 µg/mL of strontium

Standard solution: 50.0 µg/mL of strontium from the *Standard stock solution*

Sample solution: 20 mg/mL of Calcium Acetate

Linearity solution A: Dilute 20.0 mL of the *Sample solution* with water to 25.0 mL (0 µg/mL of strontium).

Linearity solution B: Dilute 2.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (4 µg/mL of strontium).

Linearity solution C: Dilute 4.0 mL of the *Standard solution* and 20.0 mL of the *Sample solution* with water to 25.0 mL (8 µg/mL of strontium).

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 460.7 nm

Lamp: Strontium hollow-cathode

Flame: Nitrous oxide–acetylene

Blank: Water

Analysis

Samples: *Linearity solutions A*, *B*, and *C*

Plot the absorbances of the *Linearity solutions* versus their content of strontium (0, 4, and 8 µg/mL), draw the straight line best fitting the three points, and extrapolate the line until it intercepts the concentration axis. From the intercept determine the amount, in µg/mL, of strontium in the *Sample solution*.

Calculate the percentage of strontium in the sample by multiplying this value by 0.00625.

Acceptance criteria: NMT 0.05%

• **Readily Oxidizable Substances**

Sample solution: 20 mg/mL of Calcium Acetate in boiling water

Analysis: Add a few glass beads to 100 mL of the *Sample solution*, 6 mL of 10 N sulfuric acid, and 0.3 mL of 1 N potassium permanganate. Mix, boil gently for 5 min, and allow the precipitate to settle.

Acceptance criteria: The pink color in the supernatant is not completely discharged.

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: 50 mg/mL

Acceptance criteria: 6.3–9.6

• **Water Determination,** *Method I* ⟨921⟩

Sample: 0.100 g

Analysis: Proceed as directed in the chapter, adding 2 mL of glacial acetic acid to the titration vessel in addition to the methanol.

Acceptance criteria: NMT 7.0%

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Where Calcium Acetate is intended for use in hemodialysis or peritoneal dialysis, it is so labeled.

• **USP Reference Standards** ⟨11⟩

USP Sodium Fluoride RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(3)

Current DocID: GUID-D4C8EE04-D86B-4067-A40F-B09840F5B7E6_5_en-US

DOI: https://doi.org/10.31003/USPNF_M11400_05_01
DOI ref: 2h91h