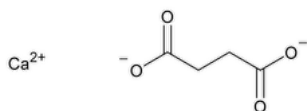


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Calcium Succinate



$C_4H_4CaO_4 \cdot H_2O$ 174.17

Butanedioic acid, calcium salt (1:1), monohydrate;

Calcium succinate monohydrate CAS RN®: 159389-75-0; UNII: 158D828FC0.

Anhydrous CAS RN®: 140-99-8; UNII: P455B96DTZ.

DEFINITION

Calcium Succinate contains NLT 98.0% and NMT 102.0% of calcium succinate ($C_4H_4CaO_4$), calculated on the dried basis.

IDENTIFICATION

- **A.** [IDENTIFICATION TESTS—GENERAL, Calcium\(191\)](#).

Sample solution: 20 mg/mL

Acceptance criteria: Meets the requirements

Change to read:

- **B.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)

ASSAY

PROCEDURE

Sample: 650 mg of Calcium Succinate

Titrimetric system

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

Mode: Direct titration

Titrant: 0.1 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* into a 250-mL beaker, add 100 mL of water and 2 mL of concentrated hydrochloric acid, and stir using a magnetic stirring bar. While stirring, add 30 mL of *Titrant* from the titration buret, and 25 mL of 2 N sodium hydroxide. Check the pH of the solution and make sure it is between 12.0 and 13.0. Add 300–500 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Perform a blank determination.

Calculate the percentage of calcium succinate ($C_4H_4CaO_4$) 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, 156.15 mg/mmol

W = *Sample* weight (mg)

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

IMPURITIES

- [CHLORIDE AND SULFATE, Chloride\(221\)](#).

Standard solution: 1.0 mL of 0.010 N hydrochloric acid

Sample: 1.8 g

Acceptance criteria: NMT 0.02%

- [CHLORIDE AND SULFATE, Sulfate\(221\)](#).

Standard solution: 1.0 mL of 0.020 N sulfuric acid

Sample: 2.0 g

Acceptance criteria: NMT 0.05%

• [ELEMENTAL IMPURITIES—PROCEDURES \(233\)](#)

Acceptance criteria

Arsenic: NMT 3.0 µg/g

Cadmium: NMT 2.0 µg/g

Lead: NMT 2.0 µg/g

Mercury: NMT 0.1 µg/g

SPECIFIC TESTS

• [pH \(791\)](#)

Sample solution: 50 mg/mL in water. [NOTE—The solution is slurry.]

Acceptance criteria: 7.0–12.0

• [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 160° for 5 h.

Acceptance criteria: 9.0%–13.5%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Calcium Succinate RS](#)

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

Topic/Question	Contact	Expert Committee
CALCIUM SUCCINATE	Nagaphani Batchu Senior Scientist I, Documentary Standards	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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