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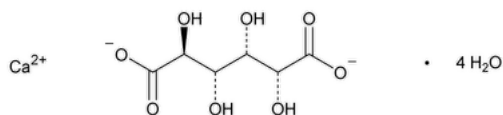
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Calcium Saccharate


 $\text{C}_6\text{H}_8\text{CaO}_8 \cdot 4\text{H}_2\text{O}$ 320.26

D-Glucaric acid, calcium salt (1:1) tetrahydrate;

Calcium D-glucarate (1:1), tetrahydrate CAS RN®: 5793-89-5.

DEFINITION

Calcium Saccharate is the calcium salt of D-saccharic acid. It contains NLT 98.5% and NMT 102.0% of $\text{C}_6\text{H}_8\text{CaO}_8 \cdot 4\text{H}_2\text{O}$.

IDENTIFICATION

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

Sample: 0.2 g**Analysis:** Dissolve the *Sample* in 10 mL of water by the addition of 2 mL of hydrochloric acid.**Acceptance criteria:** Meets the requirements

- **B. SPECTROSCOPIC IDENTIFICATION TESTS (197), [Infrared Spectroscopy: 197M](#):** Meets the requirements

ASSAY

Change to read:

PROCEDURE

Sample: 600 mg**Blank:** 150.0 mL of water**Titrimetric system**(See [Titrimetry \(541\)](#).)**Mode:** Direct titration**Titrant:** 0.05 M edetate disodium VS**Endpoint detection:** Visual**Analysis:** Dissolve the *Sample* in 150 mL of water with the aid of a sufficient volume of hydrochloric acid. While stirring, preferably with a magnetic stirrer, add 30 mL of *Titrant* from a 50-mL buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue.Continue the titration to a blue endpoint. Perform a *Blank* determination and make any necessary corrections.Calculate the percentage of calcium saccharate ($\text{C}_6\text{H}_8\text{CaO}_8 \cdot 4\text{H}_2\text{O}$) in the portion of Calcium Saccharate taken:

$$\text{Result} = \{[(V_S - V_B) \times \Delta M_{\Delta} (\text{ERR 1-Jan-2022}) \times F]/W\} \times 100$$

 V_S = *Titrant* volume consumed by the *Sample* (mL) V_B = *Titrant* volume consumed by the *Blank* (mL) ΔM_{Δ} = actual molarity of the *Titrant* (mmol/mL) $_{\Delta}$ (ERR 1-Jan-2022) F = equivalency factor, $_{\Delta}320.26 \text{ mg/mmol}_{\Delta}$ (ERR 1-Jan-2022) W = *Sample* weight (mg)**Acceptance criteria:** 98.5%–102.0%

IMPURITIES

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

Standard: 0.50 mL of 0.020 N hydrochloric acid**Sample:** 0.50 g dissolved in 10 mL of water by the addition of 2 mL of nitric acid**Acceptance criteria:** NMT 0.07%

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

Standard: 0.6 mL of 0.020 N sulfuric acid

Sample: 0.50 g dissolved in 10 mL of water by the addition of 2 mL of hydrochloric acid

Acceptance criteria: NMT 0.12%

• **SUCROSE AND REDUCING SUGARS**

Sample: 0.5 g

Analysis: Dissolve the *Sample* in 10 mL of water with the addition of 2 mL of hydrochloric acid, and boil the solution for about 2 min. Cool, add 15 mL of sodium carbonate TS, allow to stand for 5 min, and filter. Add 5 mL of the clear filtrate to about 2 mL of alkaline cupric tartrate TS, and boil for 1 min.

Acceptance criteria: No red precipitate is formed immediately.

SPECIFIC TESTS

• **OPTICAL ROTATION, *Specific Rotation*(781S).**

Sample solution: 60 mg/mL in 4.8 N hydrochloric acid that has been allowed to stand for 1 h

Acceptance criteria: +18.5° to +22.5°

ADDITIONAL REQUIREMENTS

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

• **USP REFERENCE STANDARDS (11).**

[USP Calcium Saccharate RS](#)

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

Topic/Question	Contact	Expert Committee
CALCIUM SACCHARATE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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