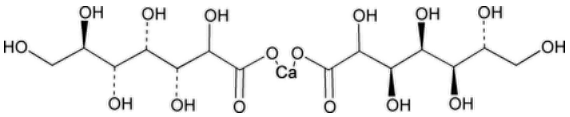
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-B4E20BF4-8E98-435C-A033-FA38B79A86B1_4_en-US
DOI: https://doi.org/10.31003/USPNF_M11600_04_01
DOI Ref: z3yrq

Calcium Gluceptate



$C_{14}H_{26}CaO_{16}$(anhydrous) 490.42

Glucoheptonic acid, calcium salt (2:1);

Calcium glucoheptonate (1:2) CAS RN®: 29039-00-7; UNII: L11651398J.

DEFINITION

Calcium Gluceptate is anhydrous or contains varying amounts of water of hydration. It consists of the calcium salt of the alpha epimer of glucoheptonic acid or of a mixture of the alpha and beta epimers of glucoheptonic acid. It contains NLT 95.0% and NMT 102.0% of calcium gluceptate ($C_{14}H_{26}CaO_{16}$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **B.** **Identification Tests—General, *Calcium*⟨191⟩:** A 20-mg/mL solution meets the requirements.

ASSAY

• **Procedure**

Sample: 800 mg of Calcium Gluceptate

Blank: 150 mL of water containing 2 mL of 3 N hydrochloric acid

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* with 150 mL of water containing 2 mL of 3 N hydrochloric acid. While stirring, preferably with a magnetic stirrer, add 25 mL of *Titrant* from the titration buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Perform the *Blank* determination.

Calculate the percentage of calcium gluceptate ($C_{14}H_{26}CaO_{16}$) 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* (mM/mL)

F = equivalency factor, 490.4 mg/mM

W = *Sample* weight (mg)

Acceptance criteria: 95.0%–102.0% on the dried basis

IMPURITIES

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

Standard: 1.0 mL of 0.020 N hydrochloric acid

Sample: 1.0 g

Acceptance criteria: NMT 0.07%

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

Standard: 1.0 mL of 0.020 N sulfuric acid

Sample: 2.0 g

Acceptance criteria: NMT 0.05%

• **Reducing Sugars**

Sample: 0.50 g

Analysis: Dissolve the *Sample* in 10 mL of hot water, add 2 mL of 3 N hydrochloric acid, boil for about 2 min, and cool. Add 5 mL of sodium carbonate TS, allow to stand for 5 min, dilute with water to 20 mL, and filter. Add 5 mL of the clear filtrate to 2 mL of alkaline cupric tartrate TS, and boil for 1 min.

Acceptance criteria: No red precipitate is formed immediately.

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: 100 mg/mL

Acceptance criteria: 6.0–8.0

• **Loss on Drying** ⟨731⟩

(See *Thermal Analysis* ⟨891⟩.)

[Note—The quantity taken for the determination may be adjusted, if necessary, for instrument sensitivity. Weight loss occurring at temperatures above about 160°, indicative of decomposition, is not to be interpreted as *Loss on Drying*.]

Sample: 10–25 mg

Analysis: Determine the percentage of volatile substances by thermogravimetric analysis on an appropriately calibrated instrument. Heat the specimen under test at a rate of 5°/min in an atmosphere of nitrogen, at a flow rate of 40 mL/min. Record the thermogram to 150°.

Acceptance criteria: See *Table 1*.

Table 1

Form	Loss on Drying (%)
Anhydrous	NMT 1.0
$2H_2O$ (dihydrate)	NMT 6.9
$31/2H_2O$	NMT 11.4

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** Label to indicate whether hydrous or anhydrous; if hydrous, label to indicate also the degree of hydration.

• **USP Reference Standards** ⟨11⟩

USP Calcium Gluceptate RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 27(6)

Current DocID: GUID-B4E20BF4-8E98-435C-A033-FA38B79A86B1_4_en-US

DOI: https://doi.org/10.31003/USPNF_M11600_04_01

DOI ref: z3yrq