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Calcium Lactate Tablets

DEFINITION

Calcium Lactate Tablets contain NLT 94.0% and NMT 106.0% of the labeled amount of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$).

[NOTE—An equivalent amount of Calcium Lactate with less water of hydration may be used in place of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$) in preparing Calcium Lactate Tablets.]

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, *Calcium*⟨191⟩**

  Sample solution: A filtered solution, equivalent to 50 mg/mL of calcium lactate pentahydrate from powdered Tablets

  Acceptance criteria: Meet the requirements

- **B. IDENTIFICATION TESTS—GENERAL, *Lactate*⟨191⟩**

  Sample solution: A filtered solution, equivalent to 50 mg/mL of calcium lactate pentahydrate from powdered Tablets

  Acceptance criteria: Meet the requirements

ASSAY

- **PROCEDURE**

  Sample: A portion of the powder from NLT 20 finely powdered Tablets, equivalent to 350 mg of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$)

  Blank: Proceed as directed in the *Analysis* without the *Sample*.

  Titrimetric system

  (See *Titrimetry* ⟨541⟩.)

  Mode: Direct titration

  Titrant: 0.05 M edetate disodium VS

  Indicator: Hydroxy naphthol blue, 300 mg

  Endpoint detection: Visual

  Analysis: Transfer the *Sample* to a suitable container, and add 150 mL of water and 2 mL of 3 N hydrochloric acid. Stir, using a magnetic stirrer, for 3–5 min. While stirring, add 15 mL of *Titrant* 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. Perform a *Blank* determination.

  Calculate the percentage of the labeled amount of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$) in the portion of Tablets 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, 308.4 (mg/mM)

  W = nominal weight of calcium lactate pentahydrate in the *Sample* taken (mg)

  Acceptance criteria: 94.0%–106.0%

PERFORMANCE TESTS

- **DISSOLUTION, *Procedure for a Pooled Sample*⟨711⟩**

  Medium: Water; 500 mL

  Apparatus 1: 100 rpm

  Time: 45 min

  Analysis: Determine the amount of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$) dissolved, as directed in the *Assay*, making any necessary modifications.

  Tolerances: NLT 75% (Q) of the labeled amount of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$) is dissolved.

- **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **Labeling:** The quantity of Calcium Lactate stated in the labeling is in terms of calcium lactate pentahydrate.

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

Topic/Question	Contact	Expert Committee
CALCIUM LACTATE TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

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