B: Mix 1 g with 20 mL of water, and add sufficient 6 N acetic acid to effect solution: the resulting solution responds to the tests for *Calcium* ⟨191⟩.

Limit of acid-insoluble substances—Dissolve 2.0 g in 30 mL of 4 N hydrochloric acid, and heat to boiling. Filter the mixture, wash the residue with hot water, and ignite: the weight of the residue does not exceed 10 mg (0.5%).

Carbonate—Mix 2 g with 50 mL of water: the addition of an excess of 3 N hydrochloric acid to the mixture does not cause more than a slight effer vescence.

Heavy metals ⟨231⟩**—**Dissolve 2.0 g in 20 mL of 3 N hydrochloric acid, and evaporate on a steam bath to dr yness. Dissolve the residue in 20 mL of water, and filter. Dilute the filtrate with water to 40 mL, and to 20 mL of the resulting solution add 1 mL of 0.1 N hydrochloric acid, then add water to make 25 mL: the limit is 20 µg per g.

Limit of magnesium and alkali salts—Dissolve 0.50 g in a mixture of 30 mL of water and 10 mL of 3 N hydrochloric acid, and proceed as directed in the test for *Magnesium and alkali salts* under *Calcium Carbonate*, beginning with "heat the solution, and boil for 1 minute." The weight of the residue does not exceed 12 mg (4.8%).

Assay—Transfer about 1.5 g of Calcium Hydroxide, accurately weighed, to a beaker, and gradually add 30 mL of 3 N hydrochloric acid. When the solution is dissolved, transfer it to a 500-mL volumetric flask, rinse the beaker thoroughly, adding the rinsings to the flask, dilute with water to volume, and mix. Pipet 50 mL of the solution into a suitable container, add 100 mL of water, 15 mL of 1 N sodium hydroxide, and 300 mg of hydroxy naphthol blue, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 3.705 mg of $Ca(OH)_2$.

Calcium Hydroxide Topical Solution

» Calcium Hydroxide Topical Solution is a solution containing, in each 100 mL, not less than 140 mg of calcium hydroxide [$Ca(OH)_2$].

Prepare Calcium Hydroxide Topical Solution as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩):

Calcium Hydroxide	3 g
Purified Water	1000 mL

Add the Calcium Hydroxide to 1000 mL of cool Purified Water, and agitate the mixture vigorously and repeatedly during 1 hour. Allow the excess calcium hydroxide to settle. Dispense only the clear supernatant.

NOTE—The solubility of calcium hydroxide, which varies with the temperature at which the solution is stored, is about 170 mg per 100 mL at 15 ° and less at a higher temperature. The official concentration is based upon a temperature of 25°.

The undissolved portion of the mixture is not suitable for preparing additional quantities of Calcium Hydroxide Topical Solution.

Packaging and storage—Preserve in well-filled, tight containers, at a temperature not exceeding 25 °.

Identification—

A: It absorbs carbon dioxide from the air, a film of calcium carbonate forming on the sur face of the liquid.

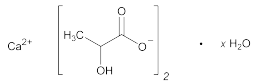
B: When heated, it becomes turbid, owing to the separation of calcium hydroxide.

C: It responds to the tests for *Calcium* ⟨191⟩.

Alkalies and their carbonates—A portion of it, saturated with carbon dioxide and subsequently boiled, is neutral in reaction.

Assay—Pipet 100 mL of T opical Solution into a suitable container, add 50 mL of water, 15 mL of 1 N sodium hydroxide, and 300 mg of hydroxy naphthol blue, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 3.705 mg of calcium hydroxide [$Ca(OH)_2$].

Calcium Lactate



$C_6H_{10}CaO_6 \cdot 5H_2O$ 308.30

$C_6H_{10}CaO_6$ 218.22

Propanoic acid, 2-hydroxy-, calcium salt (2:1), hydrate;
Calcium lactate (1:2) hydrate [41372-22-9].
Calcium lactate (1:2) pentahydrate [5743-47-5].
Anhydrous [814-80-2].

DEFINITION

Calcium Lactate contains NLT 98.0% and NMT 101.0% of calcium lactate ($C_6H_{10}CaO_6$), calculated on the dried basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL,** *Calcium* ⟨**191**⟩**:** Meets the requirements
- **B. INFRARED ABSORPTION** ⟨**197K**⟩

ASSAY

- **PROCEDURE**

Sample: Weighed portion of Calcium Lactate equivalent to 350 mg of $C_6H_{10}CaO_6$

Blank: 150 mL of water and 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* in a mixture of water and 3 N hydrochloric acid (150:2). While stirring with a magnetic stirrer, add 30 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 lactate ($C_6H_{10}CaO_6$) 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 = *Titrant* molarity (mM/mL)
F = equivalency factor, 218.2 mg/mM
W = *Sample* weight (mg)

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

- **HEAVY METALS** ⟨**231**⟩

Test preparation: Dissolve 1 g in 2.5 mL of 1 N acetic acid, and dilute with water to 25 mL.

Acceptance criteria: NMT 20 ppm

- **LIMIT OF MAGNESIUM AND ALKALI SALTS**
  Sample: 1.0 g Calcium Lactate
  Analysis: Mix the *Sample* with 40 mL of water, carefully add 1 mL of hydrochloric acid, and heat the solution to boiling. Rapidly add 40 mL of oxalic acid TS, and stir vigorously until precipitation is well established. Add immediately to the warm mixture 2 drops of methyl red TS and then 6 N ammonium hydroxide, dropwise, until the mixture is just alkaline. Cool to room temperature, transfer to a 100-mL graduated cylinder, dilute with water to 100 mL, mix, and allow to stand for 4 h or overnight. Filter, and to 50 mL of the clear filtrate in a platinum dish add 0.5 mL of sulfuric acid. Evaporate the mixture on a steam bath to a small volume. Carefully heat over a free flame to dr yness, and continue heating to complete decomposition and volatilization of ammonium salts. Finally, ignite the residue to constant weight.
  Acceptance criteria: NMT 1.0%: The weight of the residue does not exceed 5.0 mg.
- **VOLATILE FATTY ACID**
  Sample solution: Stir 500 mg of Calcium Lactate with 1 mL of sulfuric acid, and warm.
  Acceptance criteria: The mixture does not emit an odor of volatile fatty acid.

SPECIFIC TESTS

- **ACIDITY**
  Sample solution: 50 mg/mL
  Analysis: Titrate 20 mL of *Sample solution* with 0.10 N sodium hydroxide, using phenolphthalein TS as the indicator.
  Acceptance criteria: NMT 0.50 mL is required for neutralization, equivalent to NMT 0.45% as lactic acid.
- **LOSS ON DRYING** ⟨**731**⟩
  Sample: 1–2 g
  Analysis: Distribute the *Sample* evenly in a suitable weighing dish to a depth of NMT 3 mm, and dr y at 120° for 4 h.
  Acceptance criteria: See *Table 1*.

Table 1

Form	Loss on Drying (%)
Pentahydrate	22.0–27.0
Trihydrate	15.0–20.0
Monohydrate	5.0–8.0
Anhydrous	NMT 3.0

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** The label indicates whether it is the dried form or is hydrous; if the latter, the label indicates the degree of hydration. Where the quantity of Calcium Lactate is indicated in the labeling of any solution containing Calcium Lactate, this shall be understood to be in terms of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$).
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Calcium Lactate RS

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 NL T 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 30 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. Per form 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 necessar y 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.