U.S. PHARMACOPEIA

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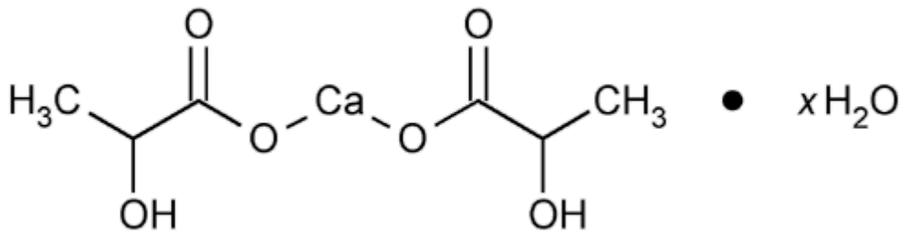
Calcium Lactate



$C_6H_{10}CaO_6 \cdot xH_2O$

(anhydrous) 218.22

Propanoic acid, 2-hydroxy-, calcium salt (2:1), hydrate.
Calcium lactate (1:2) hydrate [*41372-22-9*].

Calcium lactate (1:2) pentahydrate. 308.30 [*5743-47-5*].

Anhydrous [*814-80-2*].

» Calcium Lactate contains not less than 98.0 percent and not more than 101.0 percent of $C_6H_{10}CaO_6$, calculated on the dried basis.

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 preparation containing Calcium Lactate, this shall be understood to be in terms of calcium lactate pentahydrate ($C_6H_{10}CaO_6 \cdot 5H_2O$).

Identification—

A: A solution (1 in 20) responds to the tests for *Calcium* ⟨ 191 ⟩.

B: To 10 mg add 1 mL of sulfuric acid, and heat for 2 minutes in a water bath maintained at a temperature of 85°. Cool the solution to room temperature, add about 10 mg of 4-phenylphenol crystals, swirl, and allow to stand for about 20 minutes: a violet color develops that deepens with the passage of time.

Acidity— Titrate 20 mL of a solution (1 in 20) with 0.10 N sodium hydroxide, using phenolphthalein TS as the indicator: not more than 0.50 mL is required for neutralization (0.45% as lactic acid).

Loss on drying ⟨ 731 ⟩ **—** Distribute a 1- to 2-g portion evenly in a suitable weighing dish to a depth of not more than 3 mm, and dry at 120° for 4 hours: the pentahydrate loses between 22.0% and 27.0% of its weight; the trihydrate loses between 15.0% and 20.0% of its weight; the monohydrate loses between 5.0% and 8.0% of its weight; and the dried form loses not more than 3.0% of its weight.

Volatile fatty acid— Stir about 500 mg with 1 mL of sulfuric acid, and warm: the mixture does not emit an odor of volatile fatty acid.

Heavy metals ⟨ 231 ⟩ **—** Dissolve 1 g in 2.5 mL of 1 N acetic acid, and dilute with water to 25 mL: the limit is 0.002%.

Limit of magnesium and alkali salts— Mix 1.0 g with 40 mL of water, carefully add 1 mL of hydrochloric acid, and heat the solution to boiling. Proceed as directed in the test for *Magnesium and alkali salts* under *Calcium Carbonate*, beginning with “Rapidly add 40 mL of oxalic acid TS”: the weight of the residue does not exceed 5.0 mg (1.0%).

Organic volatile impurities, *Method I* ⟨ 467 ⟩ : meets the requirements.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
(Official January 1, 2007)

Assay— Transfer an accurately weighed amount of Calcium Lactate, equivalent to about 350 mg of $C_6H_{10}CaO_6$, to a suitable container, and dissolve in a mixture of water and 3 N hydrochloric acid (150:2). While stirring, preferably with a magnetic stirrer, add about 30 mL of 0.05 M edetate disodium VS 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. Each mL of 0.05 M edetate disodium is equivalent to 10.91 mg of $C_6H_{10}CaO_6$.

Auxiliary Information— *Staff Liaison* : Lawrence Evans, III, Ph.D., Scientist
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