

tically insoluble in ethanol (95) and in diethyl ether.

Identification (1) Dissolve 0.5 g of Calcium Gluconate in 5 mL of water by heating, add 0.65 mL of acetic acid (100) and 1 mL of freshly distilled phenylhydrazine, and heat on a water bath for 30 minutes. After cooling, scratch the inner surface of the vessel with a glass rod to induce crystallization. Collect the crystals, dissolve in 10 mL of hot water, add a small amount of activated charcoal, and filter. Cool the filtrate, scratch the inner surface of the vessel, filter the formed crystals by suction, wash with three 10 mL-portions of cold water, and dry: the crystals melt between 187°C and 199°C (with decomposition).

(2) A solution of Calcium Gluconate (1 in 40) responds to the Qualitative Tests for calcium salt.

Purity (1) Clarity of solution—Dissolve 1.0 g of Calcium Gluconate in 50 mL of water by warming: the solution is clear.

(2) Acid or alkali—Dissolve 0.50 g of Calcium Gluconate in 20 mL of water by warming. After cooling, add 0.10 mL of 0.01 mol/L hydrochloric acid VS and 2 drops of phenolphthalein TS: the solution remains colorless. To the solution add 0.30 mL of 0.01 mol/L sodium hydroxide VS: the solution turns red.

(3) Chloride—Take 0.40 g of Calcium Gluconate, and perform the test. Prepare the control solution with 0.80 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.071%).

(4) Sulfate—Take 1.0 g of Calcium Gluconate, and perform the test. Prepare the control solution with 1.0 mL of 0.005 mol/L sulfuric acid VS (not more than 0.048%).

(5) Heavy metals—Dissolve 1.0 g of Calcium Gluconate in 30 mL of water and 2 mL of dilute acetic acid by warming, cool, and add water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 2.0 mL of Standard Lead Solution, 2 mL of dilute acetic acid, and water to make 50 mL (not more than 20 ppm).

(6) Arsenic—Dissolve 0.6 g of Calcium Gluconate in 5 mL of water by warming, add 5 mL of dilute sulfuric acid and 1 mL of bromine TS, and concentrate on a water bath to 5 mL. Perform the test using Apparatus B with this solution as the test solution (not more than 3.3 ppm).

(7) Sucrose and reducing sugars—To 0.5 g of Calcium Gluconate add 10 mL of water and 2 mL of dilute hydrochloric acid, and boil the solution for 2 minutes. After cooling, add 5 mL of sodium carbonate TS, allow to stand for 5 minutes, add water to make 20 mL, and filter. To 5 mL of the filtrate add 2 mL of Fehling's TS, and boil for 1 minute: no orange-yellow to red precipitate is formed immediately.

Loss on drying Not more than 1.0% (1 g, 80°C, 2 hours).

Assay Weigh accurately about 0.4 g of Calcium Gluconate, previously dried, dissolve in 100 mL of water, add 2 mL of 8 mol/L potassium hydroxide TS and 0.1 g of NN indicator, and titrate immediately with 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS until the color of the solution changes from red-purple to blue.

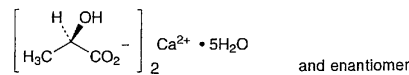
Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS

= 22.420 mg of $C_{12}H_{22}CaO_{14} \cdot H_2O$

Containers and storage Containers—Well-closed containers.

Calcium Lactate

乳酸カルシウム



$C_6H_{10}CaO_6 \cdot 5H_2O$: 308.29

Monocalcium bis[(*RS*)-2-hydroxypropanoate] pentahydrate [63690-56-2]

Calcium Lactate, when dried, contains not less than 97.0% of $C_6H_{10}CaO_6$ (mol. wt.: 218.22).

Description Calcium Lactate occurs as white powder or granules. It is odorless, and has a slightly acid taste.

A 1-g portion of it dissolves gradually in 20 mL of water, and it is slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

It is partly efflorescent at ordinary temperature, and yields the anhydride at 120°C.

Identification A solution of Calcium Lactate (1 in 20) responds to the Qualitative Tests for calcium salt and for lactate.

Purity (1) Clarity of solution—Dissolve 1.0 g of Calcium Lactate in 20 mL of water by warming: the solution is clear.

(2) Acid or alkali—To the solution obtained in (1) add 2 drops of phenolphthalein TS: no red color is produced. Then add 0.50 mL of 0.1 mol/L sodium hydroxide VS: a red color develops.

(3) Heavy metals—Dissolve 1.0 g of Calcium Lactate in 30 mL of water and 5 mL of dilute acetic acid by warming, cool, add water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution from 2.0 mL of Standard Lead Solution and 2 mL of dilute acetic acid, and dilute with water to 50 mL (not more than 20 ppm).

(4) Magnesium or alkali metals—Dissolve 1.0 g of Calcium Lactate in 40 mL of water, add 0.5 g of ammonium chloride, boil, then add 20 mL of ammonium oxalate TS. Heat the mixture on a water bath for 1 hour, cool, dilute with water to 100 mL, and filter. To 50 mL of the filtrate add 0.5 mL of sulfuric acid, evaporate to dryness, and ignite between 450°C and 550°C to constant mass: the mass of the residue is not more than 5 mg.

(5) Arsenic—Dissolve 0.5 g of Calcium Lactate in 2 mL of water and 3 mL of hydrochloric acid, and perform the test with this solution as the test solution using Apparatus B (not more than 4 ppm).

(6) Volatile fatty acid—Warm 1.0 g of Calcium Lactate with 2 mL of sulfuric acid: an odor of acetic acid or butyric acid is not perceptible.

Loss on drying 25.0–30.0% (1 g, 80°C, 1 hour at first, then 120°C, 4 hours).

Assay Weigh accurately about 0.5 g of Calcium Lactate, previously dried, add water, dissolve by heating on a water

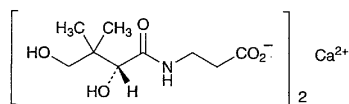
bath, cool, and add water to make exactly 100 mL. Pipet 20 mL of this solution, then 80 mL of water and 1.5 mL of 8 mol/L potassium hydroxide TS, and allow to stand for 3 to 5 minutes. Add 0.1 g of NN indicator, and titrate immediately with 0.02 mol/L disodium dihydrogen ethylenediamine tetraacetate VS until the color of the solution changes from red to blue.

Each mL of 0.02 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 4.364 mg of $C_6H_{10}CaO_6$

Containers and storage Containers—Tight containers.

Calcium Pantothenate

パントテン酸カルシウム



$C_{18}H_{32}CaN_2O_{10}$: 476.53

Monocalcium bis{3-[(2*R*)-2,4-dihydroxy-3,3-dimethylbutanoylamino]propanoate} [137-08-6]

Calcium Pantothenate, when dried, contains not less than 5.7% and not more than 6.0% of nitrogen (N: 14.01), and not less than 8.2% and not more than 8.6% of calcium (Ca: 40.08).

Description Calcium Pantothenate occurs as a white powder. It is odorless, and has a bitter taste.

It is freely soluble in water, very slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

The pH of a solution of Calcium Pantothenate (1 in 20) is between 7.0 and 9.0.

It is hygroscopic.

Identification (1) Dissolve 0.05 g of Calcium Pantothenate in 5 mL of sodium hydroxide TS, and filter. To the filtrate add 1 drop of copper (II) sulfate TS: a deep blue color develops.

(2) To 0.05 g of Calcium Pantothenate add 5 mL of sodium hydroxide TS, and boil for 1 minute. After cooling, add diluted hydrochloric acid (1 in 10) to adjust the solution to a pH between 3 and 4, and add 2 drops of iron (III) chloride TS: a yellow color is produced.

(3) A solution of Calcium Pantothenate (1 in 10) responds to the Qualitative Tests for calcium salt.

Optical rotation $[\alpha]_D^{20}$: +25.0 – +28.5° (after drying, 1 g, water, 20 mL, 100 mm).

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Calcium Pantothenate in 20 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of Calcium Pantothenate according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Alkaloids—Dissolve 0.05 g of Calcium Pantothenate in 5 mL of water, add 0.5 mL of hexaammonium hep-

tamolybdate TS and 0.5 mL of a solution of phosphoric acid (1 in 10): no white turbidity is produced.

Loss on drying Not more than 5.0% (1 g, 105°C, 4 hours).

Assay (1) Nitrogen—Proceed with about 0.05 g of Calcium Pantothenate, previously dried and accurately weighed, as directed under Nitrogen Determination.

(2) Calcium—Weigh accurately about 0.4 g of Calcium Pantothenate, previously dried, and dissolve in 30 mL of water by warming. After cooling, add exactly 25 mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS, then 10 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and 0.04 g of eriochrome black T-sodium chloride indicator, and titrate the excess disodium dihydrogen ethylenediamine tetraacetate with 0.05 mol/L magnesium chloride VS until the color of the solution changes from blue-purple to red-purple. Perform a blank determination.

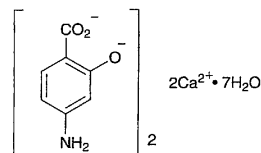
Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 2.0039 mg of Ca

Containers and storage Containers—Tight containers.

Calcium Para-aminosalicylate

Pas-calcium

パラアミノサリチル酸カルシウム



$C_{14}H_{10}Ca_2N_2O_6 \cdot 7H_2O$: 508.50

Dicalcium bis(4-amino-2-oxidobenzoate) heptahydrate [133-15-3, anhydride]

Calcium Para-aminosalicylate contains not less than 58.4% and not more than 62.0% of para-aminosalicylic acid ($C_7H_7NO_3$: 153.14), and not less than 15.3% and not more than 16.9% of calcium (Ca: 40.08).

Description Calcium Para-aminosalicylate occurs as a white to slightly colored powder. It is odorless, and has a slightly bitter taste.

It is very slightly soluble in water, and practically insoluble in ethanol (95), in acetone and in chloroform.

A saturated solution of Calcium Para-aminosalicylate is alkaline.

Identification (1) To 3 g of Calcium Para-aminosalicylate add 15 mL of ammonium chloride TS and 15 mL of water, heat on a water bath for 10 minutes: the most part of it dissolves and the gas evolved changes moistened red litmus paper to blue.

(2) To 0.05 g of Calcium Para-aminosalicylate add 100 mL of water, shake well, and filter. To 10 mL of the filtrate