

$$\begin{aligned} & \text{Amount (mg) of santonin (C}_{15}\text{H}_{18}\text{O}_3) \\ &= \text{amount (mg) of santonin for assay} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

(2) **Kainic acid**—Weigh accurately about 1.25 g of Kainic Acid and Santonin Powder, add 20 mL of diluted pyridine (1 in 10), shake thoroughly for 5 minutes, and filter. Wash the residue with three 10-mL portions of diluted pyridine (1 in 10), and filter. Combine the filtrate and the washings, and add diluted pyridine (1 in 10) to make exactly 50 mL. Pipet 2 mL of this solution, add diluted pyridine (1 in 10) to make exactly 25 mL, and use this solution as the sample solution. Dissolve about 0.025 g of kainic acid for assay, previously dried at 105°C for 4 hours and accurately weighed, in diluted pyridine (1 in 10) to make exactly 50 mL. Pipet 2 mL of this solution, add diluted pyridine (1 in 10) to make exactly 25 mL, and use this solution as the standard solution. Pipet 2 mL each of the sample solution and the standard solution, add 2 mL of ninhydrin-L-ascorbic acid TS, and heat on a water bath for 30 minutes. After cooling immediately, shake vigorously for 2 minutes, add water to make exactly 20 mL, and allow to stand for 15 minutes. Determine the absorbances, A_T and A_S , of these solutions at 425 nm as directed under the Ultraviolet-visible Spectrophotometry, using the solution prepared in the same manner with 2 mL of diluted pyridine (1 in 10) instead of the sample solution as the blank.

$$\begin{aligned} & \text{Amount (mg) of kainic acid (C}_{10}\text{H}_{15}\text{NO}_4 \cdot \text{H}_2\text{O}) \\ &= \text{amount (mg) of kainic acid for assay} \\ & \quad \times \frac{A_T}{A_S} \times 1.0845 \end{aligned}$$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Kaolin

カオリン

Kaolin is a native, hydrous aluminum silicate.

Description Kaolin occurs as white or nearly white, fragmentary masses or powder. It has a slightly clay-like odor.

It is practically insoluble in water, in ethanol (99.5) and in diethyl ether.

It is insoluble in dilute hydrochloric acid and in sodium hydroxide TS.

When moistened with water, it darkens and becomes plastic.

Identification (1) Heat 1 g of Kaolin with 10 mL of water and 5 mL of sulfuric acid in a porcelain dish, and evaporate the mixture nearly to dryness. Cool, add 20 mL of water, boil for 2 to 3 minutes, and filter: the color of the residue is gray.

(2) The filtrate obtained in (1) responds to the Qualitative Tests (1), (2) and (4) for aluminum salt.

Purity (1) **Acid or alkali**—Add 25 mL of water to 1.0 g of Kaolin, agitate thoroughly, and filter: the pH of the filtrate is between 4.0 and 7.5.

(2) **Acid-soluble substances**—Add 20 mL of dilute hydrochloric acid to 1.0 g of Kaolin, agitate for 15 minutes, and filter. Evaporate 10 mL of the filtrate to dryness, and heat strongly between 450°C and 550°C to constant mass: the mass of the ignited residue is not more than 0.010 g.

(3) **Carbonate**—Stir 1.0 g of Kaolin with 5 mL of water, then add 10 mL of diluted sulfuric acid (1 in 2): no effervescence occurs.

(4) **Heavy metals**—Boil 1.5 g of Kaolin gently with 50 mL of water and 5 mL of hydrochloric acid for 20 minutes with frequent agitation, cool, centrifuge, and separate the supernatant liquid. Wash the precipitate twice with 10 mL of water, centrifuge each time, and combine the supernatant liquid and the washings. Add dropwise ammonia solution (28) to this solution until a slight precipitate occurs, then add dilute hydrochloric acid dropwise while agitating strongly to complete solution. Add 0.45 g of hydroxylammonium chloride, and heat. Cool, add 0.45 g of sodium acetate trihydrate and 6 mL of dilute acetic acid, filter if necessary, and wash with 10 mL of water. Combine the filtrate and the washings, and add water to make 150 mL. Perform the test using 50 mL of this solution as the test solution. To 2.5 mL of Standard Lead Solution add 0.15 g of hydroxylammonium chloride, 0.15 g of sodium acetate trihydrate, 2 mL of acetic acid (31) and water to make 50 mL, and use this solution as the control solution (not more than 50 ppm).

(5) **Iron**—Add 10 mL of dilute hydrochloric acid to 0.040 g of Kaolin, and heat for 10 minutes with shaking in a water bath. After cooling, add 0.5 g of L-tartaric acid, dissolve with shaking, prepare the test solution with this solution according to Method 2, and perform the test according to Method B. Prepare the control solution with 2.0 mL of Standard Iron Solution (not more than 500 ppm).

(6) **Arsenic**—Add 5 mL of water and 1 mL of sulfuric acid to 1.0 g of Kaolin, and heat on a sand bath until white fumes begin to evolve. Cool, and add water to make 5 mL. Perform the test using Apparatus B with this solution as the test solution (not more than 2 ppm).

(7) **Foreign matter**—Place 5 g of Kaolin in a beaker, add 100 mL of water, stir, and decant to leave sand. Repeat this procedure several times with 100-mL portions of water: no sandy residue remains.

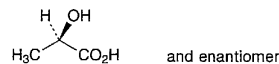
Loss on ignition Not more than 15.0% (1 g, 600°C, 5 hours).

Plasticity Add 7.5 mL of water to 5.0 g of Kaolin, and agitate thoroughly: the resultant mass has no remarkable fluidity.

Containers and storage Containers—Well-closed containers.

Lactic Acid

乳酸



$\text{C}_3\text{H}_6\text{O}_3$: 90.08

(*R,S*)-2-Hydroxypropanoic acid [50-21-5]

Lactic Acid is a mixture of lactic acid and lactic anhydride. It contains not less than 85.0% and not more than 92.0% of $C_3H_6O_3$.

Description Lactic Acid occurs as a clear, colorless or light yellow, viscous liquid. It is odorless or has a faint, unpleasant odor.

It is miscible with water, with ethanol (95) and with diethyl ether.

It is hygroscopic.

Specific gravity d_{20}^{20} : about 1.20

Identification A solution of Lactic Acid (1 in 50) changes blue litmus paper to red and responds to the Qualitative Tests for lactate.

Purity (1) Chloride—Perform the test with 1.0 g of Lactic Acid. Prepare the control solution with 1.0 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.036%).

(2) Sulfate—Perform the test with 2.0 g of Lactic Acid. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.010%).

(3) Heavy metals—To 2.0 g of Lactic Acid add 10 mL of water and 1 drop of phenolphthalein TS, and add ammonia TS dropwise until a pale red color appears. Add 2 mL of dilute acetic acid and 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 10 ppm).

(4) Iron—Prepare the test solution with 4.0 g of Lactic Acid according to Method 1, and perform the test according to Method A. Prepare the control solution with 2.0 mL of Standard Iron Solution (not more than 5 ppm).

(5) Sugars—To 1.0 g of Lactic Acid add 10 mL of water, and neutralize with sodium hydroxide TS. Boil the mixture with 10 mL of Fehling's TS for 5 minutes: no red precipitate is produced.

(6) Citric, oxalic, phosphoric and L-tartaric acid—To 1.0 g of Lactic Acid add 1.0 mL of water, followed by 40 mL of calcium hydroxide TS. Boil the mixture for 2 minutes: no change occurs.

(7) Glycerin or mannitol—Shake 10 mL of Lactic Acid with 12 mL of diethyl ether: no turbidity is produced.

(8) Volatile fatty acids—Warm Lactic Acid: it does not produce any acetic acid-like or butyric acid-like odor.

(9) Cyanide—Transfer 1.0 g of Lactic Acid to a Nessler tube, add 10 mL of water and 1 drop of phenolphthalein TS, add dropwise a solution of sodium hydroxide (1 in 10) by shaking until a pale red color develops, add 1.5 mL of a solution of sodium hydroxide (1 in 10) and water to make 20 mL, and heat in a water bath for 10 minutes. Cool, add dropwise dilute acetic acid until a red color of the solution disappears, add 1 drop of dilute acetic acid, add 10 mL of phosphate buffer solution, pH 6.8, and 0.25 mL of sodium toluenesulfon-chloramide TS, stopper immediately, mix gently, and allow to stand for 5 minutes. To the solution add 15 mL of pyridine-pyrazolone TS and water to make 50 mL, and allow to stand at 25°C for 30 minutes: the solution has no more color than the following control solution.

Control solution: Pipet 1.0 mL of Standard Cyanide Solution, and add water to make exactly 20 mL. Transfer 1.0 mL of this solution to a Nessler tube, add 10 mL of water and 1 drop of phenolphthalein TS, and proceed as directed in the sample solution.

(10) Readily carbonizable substances—Superimpose slowly 5 mL of Lactic Acid, previously kept at 15°C, upon 5 mL of sulfuric acid for readily carbonizable substances, previously kept at 15°C, and allow to stand at 15°C for 15 minutes: no dark color develops at the zone of contact.

Residue on ignition Not more than 0.10% (1 g).

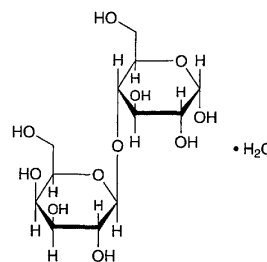
Assay Weigh accurately about 3 g of Lactic Acid, transfer in a conical flask, add accurately measured 40 mL of 1 mol/L sodium hydroxide VS, invert a watch glass over the flask, and heat on a water bath for 10 minutes. Titrate the excess sodium hydroxide with 0.5 mol/L sulfuric acid VS immediately (indicator: 2 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 1 mol/L sodium hydroxide VS
= 90.08 mg of $C_3H_6O_3$

Containers and storage Containers—Tight containers.

Lactose

乳糖



$C_{12}H_{22}O_{11} \cdot H_2O$: 360.31
4-*O*- β -D-Galactopyranosyl- α -D-glucopyranose
monohydrate [10039-26-6]

The label states the effect where it is the granulated powder.

Description Lactose occurs as white, crystals, powder or granulated powder. It is odorless.

It is freely soluble in water, and practically insoluble in ethanol (95).

Identification (1) Determine the infrared absorption spectrum of Lactose, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Lactose Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(2) To 25 mg each of Lactose and lactose monohydrate add diluted methanol (3 in 5) to make 50 mL each, and use these solutions as the sample solution and the standard solution (1), respectively. Separately, dissolve 25 mg each of glucose, lactose monohydrate, fructose and sucrose in diluted methanol (3 in 5) to make 50 mL, and use this solution as the standard solution (2). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 2 μ L each of the sample solution, the standard solution (1) and the standard solution (2) on a plate of silica gel for thin-layer