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 toluensulfonchloramide 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).

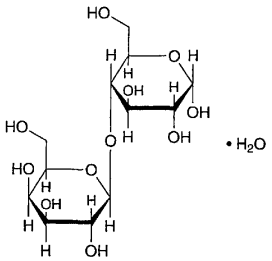
Assay Weigh accurately about 3 g of Lactic Acid, transfer in a conical flask, add accurately measured 40 mL of 1 mol/L sodium hydroxide VS, invert a watch glass over the flask, and heat on a water bath for 10 minutes. Titrate the excess sodium hydroxide with 0.5 mol/L sulfuric acid VS immediately (indicator: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



$C_{12}H_{22}O_{11}.H_2O$: 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 monahydrate 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 monahydrate, 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 μL each of the sample solution, the standard solution (1) and the standard solution (2) on a plate of silica gel for thin-layer

chromatography, and dry the spots completely. Develop the plate with a mixture of 1,2-dichloroethane, acetic acid (100), methanol and water (10:5:3:2) to a distance of about 15 cm, and dry the plate with a current of warm air. Repeat the development of the plate immediately in the same manner with the developing solvent newly replaced, and dry the plate with a current of warm air. Spray evenly on the plate a solution of 0.5 g of thymol in 100 mL of a mixture of ethanol (95) and sulfuric acid (19:1), and heat the plate at 130°C for 10 minutes: the principal spot from the sample solution is similar in position, color and size to the principal spot from the standard solution (1), and the four spots from the standard solution (2) are clearly separated.

(3) Dissolve 0.25 g of Lactose in 5 mL of water, add 3 mL of ammonia solution (28), and heat in a water bath at 80°C for 10 minutes: a red color develops.

Optical rotation $[\alpha]_D^{20}$: +54.4 - +55.9°. Weigh accurately about 10 g of Lactose, calculated on the anhydrous basis, dissolve in 80 mL of water warmed to 50°C, and add 0.2 mL of ammonia TS after cooling. After standing for 30 minutes, add water to make exactly 100 mL, and determine the optical rotation of this solution in a 100-mm cell.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Lactose in 10 mL of hot water: the solution is clear, and colorless or nearly colorless. Determine the absorbance at 400 nm of this solution as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank: not more than 0.04.

(2) Acid or alkali—Dissolve 6 g of Lactose in 25 mL of freshly boiled and cooled water by heating, and after cooling, add 0.3 mL of phenolphthalein TS: the solution is colorless. To this solution add 0.4 mL of 0.1 mol/L sodium hydroxide VS: a red color develops.

(3) Heavy metals—Dissolve 4.0 g of Lactose in 20 mL of warm water, add 1 mL of 0.1 mol/L hydrochloric acid TS and water to make 50 mL. Proceed with this solution according to Method 1, and perform the test. Prepare the control solution with 1 mL of 0.1 mol/L hydrochloric acid TS and 2.0 mL of Standard Lead Solution (not more than 5 ppm).

(4) Light absorbing substances—Dissolve 1.0 g of Lactose in water to make 100 mL, and determine the absorbances as directed under the Ultraviolet-visible Spectrophotometry: not more than 0.25 at between 210 nm and 220 nm, and not more than 0.07 at between 270 nm and 300 nm.

Loss on drying Not more than 0.5% (1 g, 80°C, 2 hours). (For the granulated powder, not more than 1.0%.)

Water 4.5 - 5.5% (1 g, direct titration. Use a mixture of methanol for Karl Fischer method and formamide for Karl Fischer method (2:1) instead of methanol for Karl Fischer method). (For the granulated powder, 4.0 - 5.5%.)

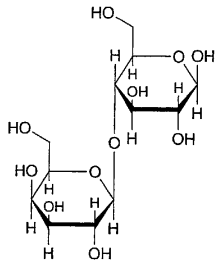
Residue on ignition Not more than 0.10% (1 g).

Microbial limit Proceed with Lactose as directed under the Microbial Limit Test: the total viable aerobic microbial count is not more than 100 per g, and the total count of fungi and yeast is not more than 50 per g. *Salmonella* and *Escherichia coli* should not be observed.

Containers and storage Containers—Well-closed containers.

Anhydrous Lactose

無水乳糖



$C_{12}H_{22}O_{11}$: 342.30

4-*O*-*β*-D-Galactopyranosyl-*β*-D-glucopyranose [*63-42-3*]

Anhydrous Lactose is *β*-lactose or a mixture of *β*-lactose and *α*-lactose.

The relative quantities of *β*-lactose in Anhydrous Lactose is indicated as the isomer ratio.

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

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

Identification **(1)** Determine the infrared absorption spectrum of Anhydrous 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 Anhydrous Lactose Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(2) To 25 mg each of Anhydrous Lactose and anhydrous lactose 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, anhydrous lactose, fructose and sucrose in diluted methanol and water (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 chromatography, and dry the spots completely. Develop the plate with a mixture of 1,2-dichloroethane, acetic acid (100), methanol and water (10:5:3:2) to a distance of about 15 cm, and dry the plate with a current of warm air. Repeat the development of the plate immediately in the same manner with the developing solvent newly replaced, and dry the plate with a current of warm air. Spray evenly on the plate a solution of 0.5 g of thymol in 100 mL of a mixture of ethanol (95) and sulfuric acid (19:1), and heat the plate at 130°C for 10 minutes: the principal spot from the sample solution is similar in position, color and size to the principal spot from the standard solution (1), and the four spots from the standard solution (2) are clearly separated.

(3) Dissolve 0.25 g of Anhydrous Lactose in 5 mL of water, add 3 mL of ammonia solution (28), and heat in a water bath at 80°C for 10 minutes: a red color develops.

Optical rotation $[\alpha]_D^{20}$: +54.4 - +55.9°. Weigh accurately