for 10 minutes. Then centrifuge at a rate of 1800 revolutions per minute for 20 minutes, separate the supernatant liquid (isopropyl myristate layer), and determine the pH of the residual water layer: not less than 5.5.

Treat isopropyl myristate which meets the requirements of pH determination as follows: 500 mL of isopropyl myristate, which has met the requirements of pH determination, is percolated through a 15-cm high layer of activated alumina filled in a glass column 20 mm in diameter and 20 cm in length with a slightly positive pressure in order to facilitate adequate flow, and then sterilized by filtration.

Isopropyl *p*-aminobenzoate See isopropyl 4-aminobenzoate.

Isopropyl 4-aminobenzoate $NH_2C_6H_4COOCH(CH_3)_2$ Pale brown crystals.

Melting point: 83 - 86°C

Isopropyl *p*-hydroxybenzoate See isopropyl parahydroxybenzoate.

Isopropyl parahydroxybenzoate $C_{10}H_{12}O_3$ Odorless and colorless fine crystals, or white, crystalline powder. Freely soluble in ethanol (95), in acetone and in diethyl ether, and very slightly soluble in water.

Melting point: 84 - 86°C

Residue on ignition: not more than 0.1%.

Content: not less than 99.0%. Assay—Proceed as directed in the Assay under Ethyl Parahydroxybenzoate.

Each mL of 1 mol/L sodium hydroxide VS
= 180.20 mg of $C_{10}H_{12}O_3$

Isotonic sodium chloride solution [Same as the namesake monograph]

Japanese acid clay Natural hydrous aluminum silicate, grayish white powder, having a particle size of about 74 μm.

Loss on drying: not more than 10% (1 g, 105°C, 4 hours).

Water adsorbing capacity: not less than 2.5%. Weigh accurately about 10 g of Japanese acid clay in weighing bottle, allow to stand for 24 hours with cover in a chamber, in which humidity is maintained to 80% by means of sulfuric acid (specific gravity 1.19), reweigh, and determine the increase of mass of the sample.

Kainic acid $C_{10}H_{15}NO_4.H_2O$ [Same as the namesake monograph]

Kainic acid for assay [Same as the monograph Kainic Acid]

Kanamycin sulfate $C_{18}H_{36}N_4O_{11}.xH_2SO_4$ [Same as the namesake monograph]

Karl Fischer TS See the Water Determination under the General Tests, Processes and Apparatus.

Kerosene It is mainly a mixture of hydrocarbons in the methane series, and a colorless, clear liquid, having not a disagreeable, characteristic odor.

Specific gravity: about 0.80

Distilling range: 180 - 300°C

Kininogen Produced by purifying from bovine plasma. Dissolve an appropriate amount of kininogen in 0.02 mol/L phosphate buffer solution, pH 8.0 so that 10 mL of the solution contains 1 mg of kininogen, and use this solution as the sample solution. Perform the following tests with the sample solution: it meets the requirement of each test.

(i) Immediately after the sample solution is prepared, add 0.1 mL of a solution of trichloroacetic acid (1 in 5) to 0.5 mL of the sample solution, shake, and centrifuge. To 0.5 mL of the supernatant liquid add 0.5 mL of gelatin-tris buffer solution, pH 8.0, and shake. To 0.1 mL of this solution add 1.9 mL of trichloroacetic acid-gelatin-tris buffer solution. Proceed with 0.1 mL of this solution as directed in the Purity (2) under Kallidinogenase, and determine the amount of kinin: kinin is not detected.

(ii) Warm 0.5 mL of the sample solution at 30 ± 0.5°C for 20 minutes, and proceed as directed in (i): kinin is not detected.

(iii) Perform the test with 0.5 mL of the sample solution as directed in the Purity (2) under Kallidinogenase: the decomposition of bradykinin is not observed.

(iv) To 0.5 mL of the sample solution add 0.5 mL of 0.02 mol/L phosphate buffer solution, pH 8.0 containing 500 μg of crystal trypsin, previously warmed at 30 ± 0.5°C for 5 minutes, warm this solution at 30 ± 0.5°C for 5 minutes, add 0.2 mL of a solution of trichloroacetic acid (1 in 5), and shake. Then boil for 3 minutes, cool in ice immediately, and centrifuge. To 0.5 mL of the supernatant liquid add 0.5 mL of gelatin-tris buffer solution, pH 8.0, and shake. To 0.1 mL of this solution add 0.9 mL of trichloroacetic acid-gelatin-tris buffer solution. To 0.1 mL of this solution add trichloroacetic acid-gelatin-tris buffer solution to make 20 mL, then proceed as directed in (i), and determine the amount, B_K, of kinin per well. Calculate the kinin-releasing activity per mg by the following equation: not less than 10 μg bradykinin equivalent per mg.

Kinin-releasing activity per mg (μg bradykinin equivalent/mg) = $B_K \times 0.0096$

Kininogen TS Dissolve a sufficient quantity of kininogen in 0.02 mol/L phosphate buffer solution, pH 8.0 to prepare a solution having an ability in each mL to release kinin corresponding to not less than 1 μg of bradykinin.

Lactic acid $CH_3CH(OH)COOH$ [K 8726, Special class]

Lactic acid TS Dissolve 12.0 g of lactic acid in water to make 100 mL.

***β*-Lactoglobulin** Prepare from milk. White to light yellow powder.

Nitrogen content: not less than 14% (calculated on the dried basis, as directed under the Nitrogen Determination).

Lactose See lactose monohydrate.

***α*-Lactose and *β*-lactose mixture (1:1)** Use a mixture of lactose monohydrate and anhydrous lactose (3:5).

Lactose broth After adding lactose monohydrate to ordinary broth in the ratio of 0.5%, add about 12 mL of bromothymol blue-sodium hydroxide TS to 1000 mL of the medium. Then dispense portions of about 10 mL into tubes for fermentation, and sterilize fractionally on each of three successive days for 15 to 30 minutes at 100°C by using an autoclave, or sterilize by autoclaving for not more than 20 minutes at 121°C, and cool quickly by immersing in cold water.

Lactose broth, three times concentrated Add lactose monohydrate to ordinary broth prepared by using 330 mL in place of 1000 mL of water in the ratio of 1.5%, and prepare according to the method of preparation under lactose broth, with 25 mL portions in tubes for fermentation.

Lactose broth, twice concentrated Add lactose monohydrate to ordinary broth prepared by using 500 mL in place of 1000 mL of water in the ratio of 1.0% and prepare according to the method of preparation under lactose broth.

Lactose monohydrate $C_{12}H_{22}O_{11}.H_2O$ [Same as the monograph Lactose].

Lactose substrate TS Dissolve 6.0 g of lactose monohydrate in diluted disodium hydrogenphosphate-citric acid buffer solution, pH 4.5 (1 in 10) to make 100 mL.

Lauromacrogol [Same as the namesake monograph in Part II]

Lead acetate See lead (II) acetate trihydrate.

Lead acetate paper See lead (II) acetate paper.

Lead (II) acetate paper Usually, immerse strips of filter paper, 6 cm × 8 cm in size, in lead acetate TS, drain off the excess liquid, and dry the paper at 100°C, avoiding contact with metals.

Lead acetate TS See lead (II) acetate TS.

Lead (II) acetate TS To 9.5 g of lead (II) acetate trihydrate add freshly boiled and cooled water to make 100 mL. Preserve in tightly stoppered bottles (0.25 mol/L).

Lead dioxide See lead (IV) oxide.

Lead (II) acetate trihydrate $Pb(CH_3COO)_2.3H_2O$ [K 8374, Special class]

Lead (II) nitrate $Pb(NO_3)_2$ [K 8563, Special class]

Lead (II) oxide PbO [K 8090, Special class]

Lead (IV) oxide PbO_2 [K 8704: 1994, Special class]

Lead monoxide See lead (II) oxide.

Lead nitrate See lead (II) nitrate.

Lead subacetate TS Place the yellowish mixture, obtained by triturating 3 g of lead (II) acetate trihydrate and 1 g of lead (II) oxide with 0.5 mL of water, in a beaker, and heat on a water bath, covering with a watch glass, until it shows a homogeneous, white to reddish white color. Then add 9.5 mL of hot water in small portions, cover it again with a watch glass, and set it aside. Decant the supernatant liquid, and adjust the specific gravity to 1.23 to 1.24 (15°C) by adding water. Preserve in tightly stoppered bottles.

Lead subacetate TS, dilute To 2 mL of lead subacetate TS add freshly boiled and cooled water to make 100 mL. Prepare before use.

L-Leucine $C_6H_{13}NO_2$ [Same as the namesake monograph]

Levallorphan tartrate for assay $C_{19}H_{25}NO.C_6H_6O_6$ [Same as the monograph Levallorphan Tartrate. When dried, it contains not less than 99.0% of $C_{19}H_{25}NO.C_6H_6O_6$.]

Levothyroxine sodium $C_{15}H_{11}I_4NNaO_4.xH_2O$ [Same as the namesake monograph]

Levothyroxine sodium for thin-layer chromatography [Same as the monograph Levothyroxine Sodium. Proceed the test as directed in the Identification (3) under Levothyroxine Sodium: any spot other than the principal spot at the *Rf* value of about 0.26 does not appear.

Lidocaine for assay ($C_{14}H_{22}N_2O$) [same as the monograph Lidocaine]

Limonene $C_{10}H_{16}$ Clear and colorless liquid, having a specific perfume and a bitter taste.

Refractive index n_D^{20}: 1.427 - 1.474

Specific gravity d_{20}^{20}: 0.841 - 0.846

Melting point: 176 - 177°C

Purity Related substances—Dissolve 0.1 g of limonene in 25 mL of hexane and use this solution as the sample solution. Perform the test with 2 μL of the sample solution as directed under the Gas Chromatography according to the following conditions. Measure each peak area by the automatic integration method and calculate the amount of limonene: it is not less than 97.0%.

Operating conditions

Proceed the operating conditions in the Assay under Eucalyptus Oil except detection sensitivity and time span of measurement.

Detection sensitivity: Measure 1 mL of limonene, add hexane to make 100 mL, and adjust the detection sensitivity so that the peak height of limonene obtained from 2 μL of this solution is 40% to 60% of the full scale.

Time span of measurement: About 3 times as long as the retention time of limonene after the solvent peak.

Liothyronine sodium $C_{15}H_{11}I_3NNaO_4$ [Same as the namesake monograph]

Liothyronine sodium for thin-layer chromatography [Same as the monograph Liothyronine Sodium. Proceed as directed for Identification (1) under Liothyronine Sodium Tablets: any spot other than the principal spot at the *Rf* value of 0.3 to 0.4 does not appear.]

Liquid paraffin See paraffin, liquid.

Lithium acetate dihydrate $CH_3COOLi.2H_2O$ Colorless crystals.

Dilute acetic acid insoluble substances—To 40.0 g of lithium acetate dihydrate add 45 mL of water, heat in a water bath to dissolve, cool, then dissolve in dilute acetic acid, and filter by suction. Wash the filter with water, dry the filter at 105 ± 2°C for 1 hour, and weigh the mass of the residue after cooling: not more than 0.0025%.

Content: not less than 97.0%. Assay—Weigh accurately 0.3 g of lithium acetate dihydrate, add exactly 50 mL of acetic acid (100) and exactly 5 mL of acetic anhydride, dissolve by heating in a water bath, and titrate with 0.1 mol/L perchloric acid VS after cooling (potentiometric titration). Perform a blank determination in the same manner, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 10.201 mg of $CH_3COOLi.2H_2O$

Lithium bromide LiBr White crystals or crystalline powder. It is hygroscopic.

Purity (1) Chloride: not more than 0.1%.
(2) Sulfate: not more than 0.01%.

Lithium chloride LiCl [K 8162: 1992]

Lithium sulfate See lithium sulfate monohydrate.

Lithium sulfate monohydrate $Li_2SO_4.H_2O$ [K 8994, Special class]

Lithocholic acid for thin-layer chromatography $C_{24}H_{40}O_3$ White crystals or crystalline powder. Soluble in ethanol (95), in acetic acid (100) and in acetone, slightly soluble in chloroform, and practically insoluble in water. Melting point: about 186°C.

Purity Related substances—Dissolve 0.025 g of lithocholic acid for thin-layer chromatography in a mixture of chloroform and ethanol (95) (9:1) to make exactly 25 mL. Dilute 1.0 mL of this solution with a mixture of chloroform and ethanol (95) (9:1) to make exactly 100 mL. Perform the test with 10 μL of this solution as directed in the Purity (7) under Ursodeoxycholic Acid: any spot other than the principal spot with the *Rf* value of about 0.7 does not appear.

Content: 98.0%. Assay—Weigh accurately about 0.5 g of lithocholic acid for thin-layer chromatography, previously dried at 80°C for 4 hours under reduced pressure (phosphorus (V) oxide), dissolve in 40 mL of neutralized ethanol and 20 mL of water. Add 2 drops of phenolphthalein TS, titrate with 0.1 mol/L sodium hydroxide VS, add 100 mL of freshly boiled and cooled water near the end point, and continue the titration.

Each mL of 0.1 mol/L sodium hydroxide VS
= 37.658 mg of $C_{24}H_{40}H_3$

Litmus paper, blue [K 9071, Litmus paper, Blue litmus paper]

Litmus paper, red [K 9071, Litmus paper, Red litmus paper]

Locke-Ringer's TS

Sodium chloride	9.0 g
Potassium chloride	0.42 g
Calcium chloride dihydrate	0.24 g
Magnesium chloride hexahydrate	0.2 g
Sodium hydrogen carbonate	0.5 g
Dextrose	0.5 g
Water, freshly distilled with a hard-glass apparatus	a sufficient quantity
To make	1000 mL

Prepare before use. The constituents except dextrose and sodium hydrogen carbonate can be made up in concentrated stock solutions, stored in a dark place, and diluted before use.

Lysate reagent A lyophilized product obtained from amebocyte lysate of horseshoe crab (*Limulus polyphemus* or *Tachypleus tridentatus*). Amebocyte lysate preparations which do not react to β-glucans are available: they are prepared by removing the G factor reacting to β-glucans from amebocyte lysate or by inhibiting the G factor reacting system of amebocyte lysate.

Lysate TS Dissolve a lysate reagent in water for bacterial endotoxins test, or in a suitable buffer, by gentle stirring.

L-Lysine hydrochloride $C_6H_{14}N_2O_2.HCl$ [Same as the namesake monograph]

Magnesia TS Dissolve 5.5 g of magnesium chloride hexahydrate and 7 g of ammonium chloride in 65 mL of water, add 35 mL of ammonia TS, allow the mixture to stand for a few days in tightly stoppered bottles, and filter. If the solution is not clear, filter before use.

Magnesium Mg [K 8875, Special class]

Magnesium chloride See magnesium chloride hexahydrate.

Magnesium chloride hexahydrate $MgCl_2.6H_2O$ [K 8159, Special class]

Magnesium nitrate See magnesium nitrate hexahydrate.

Magnesium nitrate hexahydrate $Mg(NO_3)_2.6H_2O$ [K 8567, Special class]

Magnesium oxide MgO [K 8432, Special class]

Magnesium powder Mg [K 8876, Special class]

Magnesium sulfate See magnesium sulfate heptahydrate.

Magnesium sulfate heptahydrate $MgSO_4.7H_2O$ [K 8995, Special class]

Magnesium sulfate TS Dissolve 12 g of magnesium sulfate hexahydrate in water to make 100 mL (0.5 mol/L).

Magneson [K 8879, Special class]

Magneson TS Dissolve 0.1 g of magneson in 100 mL of *N,N*-dimethylformamide.

Magnolol for component determination $C_{18}H_{18}O_2$ Odorless white, crystals or crystalline powder. Freely soluble in methanol and in diethyl ether, and practically insoluble in water. Melting point: about 102°C.

Absorbance $E^{1\%}_{1cm}$ (290 nm): 270 - 293 [0.01 g dried for 1 hour or more tin a desiccator (silica gel), methanol, 500 mL].

Purity Related substances—(1) Dissolve 1.0 mg of magnolol for component determination in exactly 1 mL of methanol, and perform the test with this solution as directed under the Thin-layer Chromatography. Spot 10 μL of the solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography, then develop the plate with a mixture of hexane, acetone and acetic acid (100) (20:15:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): any spot other than the principal spot at the *Rf* value of about 0.5 does not appear.

(2) Dissolve 5.0 mg of magnolol for component determination in 10 mL of the mobile phase, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add the mobile phase to make exactly 100 mL, and use this solution as the standard solution (1). Perform the test with 10 μL each of the sample solution and the standard solution (1) as directed under the Liquid Chromatography according to the following conditions, and determine the area of each peak from these solutions by the automatic integration method: the total area of peaks other than the peak of magnolol from the sample solution is not larger than the peak area of magnolol from the standard solution (1).

Operating conditions

Proceed the operating conditions under Magnolia Bark except detection sensitivity and time span of measurement.

Detection sensitivity: Pipet 1 mL of the standard solution (1), add the mobile phase to make exactly 20 mL, and use this solution as the standard solution (2). Adjust the sensitivity so that the peak area of magnolol obtained with 10 μL of the standard solution (2) can be measired, and the peak area of that obtained with 10 μL of the standard solution (1) is about 20% of full-scale by the automatic integration method.

Time span of measurement: About 3 times of the retention time of magnolol after the solvent peak.

Malachite green See malachite green oxalate.

Malachite green oxalate $C_{52}H_{54}N_2O_{12}$ [K 8878, Malachite green (oxalate), Special class]

Maleic acid $C_4H_4O_4$ [K 8884, Special class]

Maltose See maltose monohydrate.

Maltose monohydrate $C_{12}H_{22}O_{11}.H_2O$ [K 8883: 1992, Special class]

Manganese dioxide MnO_2 [K 8705: 1978, First class]

D-Mannitol $C_6H_{14}O_6$ [Same as the monograph D-Mannitol]

Meat extract Concentrated extract of fresh meat of bovine, equine or other animals. A yellow-brown to dark brown paste-like mass, having a meat-like odor.

Mefruside for assay $C_{13}H_{19}ClN_2O_5S_2$ [Same as the monograph Mefruside. When dried, it contains not less than 99.0% of mefruside ($C_{13}H_{19}ClN_2O_5S_2$).]

Mentha oil [Same as the namesake monograph in Part II]

Menthol $C_{10}H_{20}O$ [Same as the monograph in Part II *dl*-Menthol or *l*-Menthol]

***l*-Menthol for assay** [Same as the monograph *l*-Menthol. It contains not less than 99.0% of $C_{10}H_{20}O$ and meets the following additional specifications.]

Optical rotation $[\alpha]_D^{20}$: −48.0 – −51.0° (2.5 g, ethanol (95), 25 mL, 100 mm).

Purity Related substances—Dissolve 0.1 g of *l*-menthol for assay in 10 mL of dichloromethane, and use this solution as the sample solution. Pipet 1 mL of this solution, add dichloromethane to make exactly 100 mL, and use this solution as the standard solution (1). Perform the test with 5 μL each of the sample solution and the standard solution (1) under the Gas Chromatography according to the following conditions, measure each peak area of these solutions by the automatic integration method: the total peak areas other than the peak area of *l*-menthol from the sample solution is not larger than the peak area of *l*-menthol from the standard solution (1).

Operatin conditions

Proceed the operating conditions in the Assay under Mentha Oil except detection sensitivity and time span of measurement.

Detection sensitivity: Pipet 1 mL of the standard solution (1), add dichloromethane to make exactly 20 mL, and use this solution as the standard solution (2). Adjust the detection sensitivity so that the peak area of *l*-menthol obtained from 5 μL of the standard solution (2) can be measured, and the peak height of *l*-menthol from 5 μL of the standard solution (1) is about 20% of the full scale.

Time span of measurement: About twice as long as the retention time of *l*-menthol after the solvent peak.

Mepivacaine hydrochloride for assay $C_{15}H_{22}N_2O.HCl$ [Same as the monograph Mepivacaine Hydrochloride. When dried, it contains not less than 99.0% of mepivacaine hydrochloride ($C_{15}H_{22}N_2O.HCl$).]

Mercapto acetic acid $HSCH_2COOH$ [K 8630, Special class] Place in an ampule, and preserve in a dark, cold place. Do not use after storing for a long period.

2-Mercaptoethanol $HSCH_2CH_2OH$ Clear and colorless liquid.

Specific gravity d_4^{20}: 1.112 – 1.117

Content: not less than 97.0%.

Mercaptopurine $C_5H_4N_4S.H_2O$ [Same as the namesake monograph]

Mercuric acetate See mercury (II) acetate.

Mercuric acetate TS for nonaqueous titration See mercury (II) acetate TS for nonaqueous titration.

Mercuric chloride See mercury (II) chloride.

Mercury Hg [K 8572, Special class]

Mercury (II) acetate $Hg(CH_3COO)_2$ [K 8369, Special class]

Mercury (II) acetate TS for nonaqueous titration Dissolve 5 g of mercury (II) acetate in acetic acid (100) for nonaqueous titration to make 100 mL.

Mercury (II) chloride $HgCl_2$ [K 8139, Special class]

Metallic sodium See sodium.

Metanil yellow $C_{18}H_{14}N_3NaO_3S$ Yellow-brown powder. Sparingly soluble in water, and very slightly soluble in ethanol (95) and in N,N-dimethylformamide. Transition interval (color change): pH 1.2 (red) – 2.3 (yellow).

Metanil yellow TS Dissolve 0.1 g of metanil yellow in 200 mL of N,N-dimethylformamide.

Metaphosphoric acid HPO_3 [K 8890, Special class]

Metaphosphoric acid-acetic acid TS Dissolve 15 g of metaphosphoric acid and 40 mL of acetic acid (100) in water to make 500 mL. Preserve in a cold place, and use within 2 days.

Metenolone enanthate $C_{27}H_{42}O_3$ [Same as the namesake monograph]

Metenolone enanthate for assay To 1 g of metenolone enanthate add 30 mL of water, and add slowly 70 mL of methanol with warming to dissolve. Filter while hot, and allow the filtrate to stand on a water bath for 30 minutes. Allow to stand overnight in a cold place, collect the crystals thus formed, and wash with a small amount of diluted methanol (1 in 3). Recrystallize in the same manner, and dry the crystals in a desiccator (in vacuum, phosphorus (V) oxide) for 4 hours. It is white, odorless crystals.