Ethanol, methanol-free See ethanol (95), methanol-free.

Ethanol, neutralized To a suitable quantity of ethanol (95) add 2 to 3 drops of phenolphthalein TS, then add 0.01 mol/L or 0.1 mol/L sodium hydroxide VS until a light red color develops. Prepare before use.

Ethanol (95) C_2H_5OH [K 8102, Special class]

Ethanol (95), methanol-free Perform the test for methanol, by using this methanol-free ethanol (95) in place of the standard solution, as directed in the Methanol Test under the General Tests, Processes and Apparatus: it is practically colorless.

Ethanol (99.5) C_2H_5OH [K 8101, Special class]

Ethenzamide $C_9H_{11}NO_2$ [Same as the namesake monograph].

Ether See diethyl ether.

Ether, anesthetic $C_2H_5OC_2H_5$ [Same as the namesake monograph]

Ether, dehydrated See diethyl ether, dehydrated.

Ether for purity of crude drug See diethyl ether for purity of crude drug.

Ethinylestradiol $C_{20}H_{24}O_2$ [Same as the namesake monograph]

***p*-Ethoxyphenol** See 4-ethoxyphenol.

4-Ethoxyphenol $C_8H_{10}O_2$ White to light yellow-brown crystals or crystalline powder. Freely soluble in ethanol (95), and very slightly soluble in water.

Melting point: 62 - 68°C

Purity—Dissolve 0.5 g of 4-Ethoxyphenol in 5 mL of ethanol (95), and use this solution as the sample solution. Perform the test 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 substance other than 4-ethoxyphenol by the area percentage method: it is not more than 2.0%.

Operating conditions

Detector: Thermal conductivity detector.

Column: A glass column about 3 mm in inside diameter and about 2 m in length, packed with 180- to 250-μm siliceous earth for gas chromatography coated with methylsilicone porymer for gas chromatography.

Column temperature: A constant temperature of about 150°C.

Carrier gas: Herium

Flow rate: Adjust the flow rate so that the retention time of 4-ethoxyphenol is about 5 minutes.

Detection sensitivity: Adjust the detection sensitivity so that the peak height of 4-ethoxyphenol obtained from 1 μL of the sample solution is not less than 50% of the full scale.

Time span of measurement: 3 times as long as the retention time of 4-ethoxyphenol after the solvent peak.

Ethyl acetate $CH_3COOC_2H_5$ [K 8361, Special class]

Ethyl aminobenzoate $C_9H_{11}NO_2$ [Same as the namesake monograph]

Ethyl benzoate $C_6H_5COOC_2H_5$ Clear, colorless liquid.

Refractive index n_D^{20}: 1.502 - 1.507

Specific gravity d_{20}^{20}: 1.045 - 1.053

Ethyl carbamate $H_2NCOOC_2H_5$ [K 8259: 1980, Special class]

Ethyl cyanoacetate $NCCH_2COOC_2H_5$ [K 8449: 1961, First class]

Ethylenediamine $C_2H_8N_2$ [Same as the namesake monograph in Part II]

Ethylenediamine TS Dissolve 70 g of ethylenediamine in 30 g of water.

Ethylene glycol $HOCH_2CH_2OH$ [K 8105, Special class]

Ethylene glycol for Karl Fischer method Distil ethylene glycol, and collect the fraction distilling between 195°C and 198°C. The water content is not more than 1.0 mg per mL.

Ethyl iodide See iodoethane.

***N*-Ethylmaleimide** $C_6H_7NO_2$ White crystals, having a pungent, characteristic odor. Freely soluble in ethanol (95), and slightly soluble in water.

Melting point: 43 - 46°C

Purity Clarity and color of solution—Dissolve 1 g of *N*-ethylmaleimide in 20 mL of ethanol (95): the solution is clear and colorless.

Content: not less than 99.0%. Assay—Dissolve about 0.1 g of *N*-ethylmaleimide, accurately weighed, in 20 mL of ethanol (95), add exactly 20 mL of 0.1 mol/L sodium hydroxide VS, and titrate with 0.1 mol/L hydrochloric acid VS (indicator: 2 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium hydroxide VS
= 12.513 mg of $C_6H_7NO_2$

Ethyl *n*-caprylate $C_{10}H_{20}O_2$ Clear and colorless to almost colorless liquid.

Specific gravity d_{20}^{20}: 0.864 - 0.871

Purity Related substances—Dissolve 0.1 g of ethyl *n*-caprylate in 10 mL of dioxane and use this solution as the sample solution. Pipet 1 mL of the sample 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) as directed under the Gas Chromatography according to the following conditions, and measure each peak area from these solutions by the automatic integration method: the total peak areas other than ethyl *n*-caprylate from the sample solution is not larger than the peak area of ethyl *n*-caprylate from the standard solution (1).

Operating 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 ethyl *n*-caprylate obtained from 5 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of ethyl *n*-caprylate from 5 μL of the standard solu-

tion (1) is about 20% of the full scale.

Time span of measurement: 3 times as long as the retention time of ethyl *n*-caprylate after the solvent peak.

Ethyl parahydroxybenzoate $HOC_6H_4COOC_2H_5$ [Same as the namesake monograph in Part II]

Ethyl propionate $CH_3CH_2COOC_2H_5$ Colorless, clear liquid.

Specific gravity d_4^{20}: 0.890 - 0.892

2-Ethyl-2-phenylmalondiamide $C_{11}H_{14}O_2N_2$ White, odorless crystals. Soluble in ethanol (95), and very slightly soluble in water.

Melting point: about 120°C (with decomposition).

Purity Related substances—To 5.0 mg of 2-ethyl-2-phenylmalondiamide add 4 mL of pyridine and 1 mL of bistrimethylsilylacetamide, shake thoroughly, and heat at 100°C for 5 minutes. After cooling, add pyridine to make exactly 10 mL, 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 conditions in the Purity (3) under Primidone: any peak other than the peaks of 2-ethyl-2-phenylmalondiamide and the solvent does not appear. Adjust the detection sensitivity so that the peak height of 2-ethyl-2-phenylmalondiamide obtained from 2 μL of the sample solution is about 80% of the full scale, and the time span of measurement is about twice as long as the retention time of 2-ethyl-2-phenylmalondiamide after the solvent peak.

Etilefrine hydrochloride $C_{10}H_{15}NO_2.HCl$ [Same as the namesake monograph]

Etilefrine hydrochloride for assay $C_{10}H_{15}NO_2.HCl$ [Same as the monograph Etilefrine Hydrochloride. When dried, it contains not less than 99.0% of etilefrine hydrochloride ($C_{10}H_{15}NO_2.HCl$).]

Famotidine for assay $C_8H_{15}N_7O_2S_3$ [Same as the monograph Famotidine. When dried, it contains not less than 99.0% of famotidine ($C_8H_{15}N_7O_2S_3$), and when proceed as directed in the Purity (3), its total related substances is not more than 0.4%.]

Fatty oil Same as the fatty oil under the monograph.

Fehling's TS The copper solution—Dissolve 34.66 g of copper (II) sulfate pentahydrate in water to make 500 mL. Keep this solution in well-filled, glass-stoppered bottles.

The alkaline tartrate solution—Dissolve 173 g of potassium sodium tartrate tetrahydrate and 50 g of sodium hydroxide in water to make 500 mL. Preserve this solution in polyethylene containers.

Before use, mix equal volumes of both solutions.

Fehling's TS for amylolytic activity test

The copper solution—Dissolve 34.660 g of copper (II) sulfate pentahydrate, accurately weighed, in water to make exactly 500 mL. Preserve this solution in well-filled, glass-stoppered bottles.

The alkaline tartrate solution—Dissolve 173 g of potassium sodium tartrate tetrahydrate and 50 g of sodium hydroxide in water to make exactly 500 mL. Preserve this solution in polyethylene containers.

Before use, mix exactly equal volumes of both solutions.

Ferric ammonium citrate See ammonium iron (III) citrate.

Ferric ammonium sulfate See ammonium iron (III) sulfate 12 water.

Ferric ammonium sulfate TS See ammonium iron (III) sulfate TS.

Ferric ammonium sulfate TS, dilute See ammonium iron (III) sulfate TS, dilute.

Ferric chloride See iron (III) chloride hexahydrate.

Ferric chloride-acetic acid TS See iron (III) chloride-acetic acid TS.

Ferric chloride-iodine TS See iron (III) chloride-iodine TS.

Ferric chloride-methanol TS See iron (III) chloride-methanol TS.

Ferric chloride-pyridine TS, anhydrous See iron (III) chloride-pyridin TS, anhydrous.

Ferric chloride TS See iron (III) chloride TS.

Ferric chloride TS, acidic See iron (III) chloride TS, acidic.

Ferric chloride TS, dilute See iron (III) chloride TS, dilute.

Ferric nitrate See iron (III) nitrate enneahydrate.

Ferric nitrate TS See iron (III) nitrate TS.

Ferric perchlorate See iron (III) perchlorate hexahydrate.

Ferric perchlorate-dehydrated ethanol TS See iron (III) perchlorate-ethanol TS.

Ferric salicylate TS Dissolve 0.1 g of ammonium iron (III) sulfate 12-water in 50 mL of diluted sulfuric acid (1 in 250), and add water to make 100 mL. Measure 20 mL of this solution, and add 10 mL of a solution of sodium salicylate (23 in 2000), 4 mL of dilute acetic acid, 16 mL of sodium acetate TS and water to make 100 mL. Prepare before use.

Ferric sulfate See iron (III) sulfate *n*-hydrate.

Ferric sulfate TS See iron (III) sulfate TS.

Ferrous ammonium sulfate See ammonium iron (II) sulfate hexahydrate.

Ferrous sulfate See iron (II) sulfate heptahydrate.

Ferrous sulfate TS See iron (II) sulfate TS.

Ferrous sulfide See iron (II) sulfide.

Ferrous tartrate TS See iron (II) tartrate TS.

Ferrous thiocyanate TS See iron (II) thiocyanate TS.

Ferrous trisodium pentacyanoamine TS See iron (II) trisodium pentacyanoamine TS.

Fibrinogen Fibrinogen is prepared from human or bovine blood by fractional precipitation with ethanol or ammonium sulfate. It may contain citrate, oxalate and sodium chloride. A white, amorphous solid. Add 1 mL of isotonic sodium chloride solution to 0.01 g of fibrinogen. It, when warmed to 37°C, dissolves with a slight turbidity, and clots

on the subsequent addition of 1 unit of thrombin.

Fixed oil Same as the vegetale oils under the monograph.

Fluocinolone acetonide $C_{24}H_{30}F_2O_6$ [Same as the namesake monograph]

Fluorescein $C_{20}H_{12}O_5$ [K 8829: 1991, Special class]

Fluorescein sodium $C_{20}H_{10}Na_2O_5$ [Same as the namesake monograph].

Fluorescein sodium TS Dissolve 0.2 g of fluorescein sodium in water to make 100 mL.

1-Fluoro-2,4-Dinitrobenzene $C_6H_3(NO_2)_2F$ [K 8479, Special class]

Fluorosilanized silica gel for liquid chromatography Prepared for liquid chromatography.

Flurazepam for assay $C_{21}H_{23}ClFN_3O$ [Same as the monograph Flurazepam. When drid, it contains not less than 99.0%of flurazepan ($C_{21}H_{23}ClFN_3O$).]

Folic acid $C_{19}H_{19}N_7O_6$ [Same as the namesake monograph]

Folin's TS Place 20 g of sodium tungstate (VI) dihydrate, 5 g of sodium molybdate dihydrate and about 140 mL of water in a 300-mL volumetric flask, add 10 mL of diluted phosphoric acid (17 in 20) and 20 mL of hydrochloric acid, and boil gently using a reflux condenser with ground-glass joints for 10 hours. To the mixture add 30 g of lithium sulfate monohydrate and 10 mL of water, and then add a very small quantity of bromine to change the deep green color of the solution to yellow. Remove the excess bromine by boiling for 15 minutes without a condenser, and cool. Add water to make 200 mL, and filter through a glass filter. Store it free from dust. Use this solution as the stock solution, and dilute with water to the directed concentration before use.

Formaldehyde solution HCHO [K 8872, Special class]

Formaldehyde solution-sulfuric acid TS Add 1 drop of formaldehyde solution to 1 mL of sulfuric acid. Prepare before use.

Formaldehyde solution TS To 0.5 mL of formaldehyde solution add water to make 100 mL.

Formalin See formaldehyde solution.

Formalin TS See formaldehyde solution TS.

Formalin-sulfuric acid TS See formaldehyde solution-sulfuric acid TS.

Formamide $HCONH_2$ [K 8873, Special class]

Formamide for Karl Fischer method $HCONH_2$ [K 8873, Special class; water content per g of formamide for Karl Fischer method should be not more than 1 mg.]

Formic acid HCOOH [K 8264, Special class, specific gravity: not less than 1.21].

Freund's complete adjuvant A suspension of 5 mg of mycobacteria of *Corynebacterium butyricum*, killed by heating, in 10 mL of a mixture of mineral oil and aricel A (17:3).

Fructose $C_6H_{12}O_6$ [Same as the namesake monograph]

Fuchsin A lustrous, green, crystalline powder or mass, slightly soluble in water and in ethanol (95).
Loss on drying: 17.5 - 20.0% (1 g, 105°C, 4 hours)
Residue on ignition: not more than 0.1% (1 g).

Fuchsin-ethanol TS Dissolve 11 g of fuchsin in 100 mL of ethanol (95).

Fuchsin-sulfurous acid TS Dissolve 0.2 g of fuchsin in 120 mL of hot water, and allow the solution to cool. Add a solution prepared by dissolving 2 g of anhydrous sodium sulfite in 20 mL of water, then add 2 mL of hydrochloric acid and water to make 200 mL, and allow to stand for at least 1 hour. Prepare before use.

Fumaric acid for thin-layer chromatography $C_4H_4O_4$ White, crystalline powder, odorless, and has a characteristic acid taste.
Purity—Perform the test as directed in the Identification (5) under Clemastine Fumarate: any spot other than the principal spot at the *Rf* value of about 0.8 does not appear.

Fuming nitric acid See nitric acid, fuming.

Fuming sulfuric acid See sulfuric acid, fuming.

Furfural $C_5H_4O_2$ [K 8833: 1978, Special class]

Galactose See D-galactose.

D-Galactose $C_6H_{12}O_6$ [K 8250: 1992, D(+)-Galactose, Special class]

Gallic acid $C_6H_2(OH)_3COOH.H_2O$ [K 8898: 1961, Special class]

Gelatin [Same as the namesake monograph in Part II]

Gelatin, acid-treated [Same as the monograph in Part II Gelatin. Its isoelectric point is at pH between 7.0 and 9.0]

Gelatin peptone See peptone, gelatin.

Gelatin-phosphate buffer solution Dissolve 13.6 g of potassium dihydrogenphosphate, 15.6 g of sodium dihydrogenphosphate dihydrate and 1.0 g of sodium azide in water to make 1000 mL, adjust the pH to 3.0 with diluted phosphoric acid (1 in 75) (solution A). Dissolve 5.0 g of acid-treated gelatin in 400 mL of the solution A by warming, after cooling, adjust the pH to 3.0 with diluted phosphoric acid (1 in 75), and add the solution-A to make 1000 mL.

Gelatin-phosphate buffer solution, pH 7.0 Dissolve 1.15 g of sodium dihydrogenphosphate dihydrate, 5.96 g of disodium hydrogenphosphate 12-water and 5.4 g of sodium chloride in 500 mL of water. Dissolve 1.2 g of gelatin to this solution by heating, and after cooling add water to make 600 mL.

Gelatin-phosphate buffer solution, pH 7.4 To 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS for buffer solution add 39.50 mL of 0.2 mol/L sodium hydroxide VS and 50 mL of water. Dissolve 0.2 g of gelatin to this solution by heating, then after cooling adjust to pH 7.4 with 0.2 mol/L sodium hydroxide TS, and add water to make 200 mL.

Gelatin-tris buffer solution Dissolve 6.06 g of 2-amino-2-hydroxymethyl-1,3-propanediol and 2.22 g of sodium chloride in 700 mL of water. Separately, dissolve 10 g of acid-treated gelatin in 200 mL of water by warming. After cooling, mix these solutions, and adjust the pH to 8.8 with dilute hydrochloric acid, and add water to make 1000 mL.

Gelatin-tris buffer solution, pH 8.0 Dissolve 40 g of 2-amino-2-hydroxymethyl-1,3-propanediol and 5.4 g of sodium chloride in 500 mL of water. Add 1.2 g of gelatin to dissolve by heating, adjust to pH 8.0 with dilute hydrochloric acid after cooling, and add water to make 600 mL.

Gelatin TS Dissolve 1 g of gelatin in 50 mL of water by gentle heating, and filter if necessary. Prepare before use.

Gel-type strong acid cation-exchange resin for liquid chromatography (degree of cross-linkage: 8 %) Prepared for liquid chromatography.

Gel type strong acid ion-exchange resin for liquid chromatography (degree of cross-linkage: 6 %) Prepared for liquid chromatography.

Geniposide for thin-layer chromatography $C_{17}H_{24}O_{10}$ White crystals or crystalline powder. Melting point: about 160°C (with decomposition).

Purity Related substances—Dissolve 1.0 mg of geniposide for thin-layer chromatography in exactly 1 mL of methanol, and perform the test with 20 μL of this solution as directed in the Identification (2) under Gardenia Fruit: any spot other than the principal spot at the *Rf* value of about 0.3 does not appear.

Gentamicin B $C_{19}H_{38}N_4O_{10}$ White to pale yellowish white powder. Very soluble in water, and practically insoluble in ethanol (95).

Content: not less than 80.0%. Assay—Dissolve a suitable amount of gentamicin B in 0.05 mol/L sulfuric acid TS to make the solution containing 0.1 mg of gentamicin B per mL, and use this solution as the sample solution. Perform the test with 5 μL of the sample solution as directed under the Liquid Chromatography according to the following conditions, and measure each peak area by the automatic integration method. Calculate the amount of gentamicin B by the area percentage method.

Operating conditions

Apparatus, detector, column, column temperature, reaction coil, mobile phase, reagent, reaction temperature, flow rate of the mobile phase, and flow rate of the reagent: Proceed the operating conditions in the Assay under Isepamicin Sulfate.

Time span of measurement: About 3 times as long as the retention time of gentamicin B.

System suitability

Proceed the system suitability in the Assay under Isepamicin Sulfate.

Gentiopicroside for thin-layer chromatography $C_{16}H_{20}O_9$ A white powder. Freely soluble in water and in methanol, and practically insoluble in diethyl ether.

Melting point: about 110°C (with decomposition).

Purity Related substances—Dissolve 0.010 g of gentiopicroside for thin-layer chromatography in 1 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and methanol to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 10 μL each of the sample solution and the standard solution as directed in the Identification under Gentian: the spots other than the principal spot at the *Rf* value of about 0.4 from the sample solution are not more intense than the spot from the standard solution.

Giemsa's TS Dissolve 3 g of azure II-eosin Y and 0.8 g of azure II in 250 g of glycerin by warming to 60°C. After cooling, add 250 g of methanol, and mix well. Allow to stand for 24 hours, and filter. Store in tightly stoppered bottles.

Azure II-eosin Y is prepared by coupling eosin Y to azure II. Azure II is the mixture of equal quantities of methylene azure (azure I), prepared by oxidizing methylene blue, and methylene blue.

[6]-Gingerol for thin-layer chromatography $C_{17}H_{26}O_4$ Yellow oil, having a pungent taste. Soluble in methanol, acetone, and diethyl ether.

Purity Related substances—Dissolve 1.0 mg of [6]-gingerol for thin-layer chromatography in exactly 1 mL of acetone. Perform the test with 10 μL of this solution as directed in the Identification under Ginger: any spot other than the principal spot at the *Rf* value of about 0.5 does not appear.

Ginsenoside Rg_1 for thin-layer chromatography $C_{42}H_{72}O_{14}$ White, crystalline powder, having a slight, bitter taste. Freely soluble in methanol and in ethanol (95), and practically insoluble in diethyl ether and in chloroform.

Melting point: 194 - 196.5°C

Purity Related substances—Dissolve 1 mg of ginsenoside Rg_1 for thin layer chromatography in 1 mL of methanol, and perform the test with 20 μL of this solution as directed in the Identification (2) under Ginseng: any spot other than the principal spot at the *Rf* value of about 0.4 does not appear.

Glacial acetic acid See acetic acid (100).

Glacial acetic acid for nonaqueous titration See acetic acid for nonaqueous titration.

Glacial acetic acid-sulfuric acid TS See acetic acid (100)-sulfuric acid TS.

Glass fiber See glass wool.

Glass wool [K 8251, Special class]

γ-Globulin A plasma protein obtained from human serum as Cohn's II and III fractions. White crystalline powder. It contains not less than 98% of γ-globulin in the total protein.

Glucose $C_6H_{12}O_6$ [Same as the namesake monograph]

Glucose detection TS Dissolve 1600 units of glucose oxidase, 0.016 g of 4-aminoantipyrine, 145 units of peroxidase and 0.27 g of *p*-hydroxybenzoic acid in tris buffer solution, pH 7.0, to make 200 mL.

Glucose detection TS for penicillium origin β-galactosidase Dissolve glucose oxidase (not less than 500 units), peroxidase (not less than 50 units), 0.01 g of 4-aminoantipyrine and 0.1 g of phenol in phosphate buffer, pH 7.2 to make 100 mL.

Glucose oxidase Obtained from *Aspergillus nigar*. White powder. It is freely soluble in water. It contains about