mol/L sodium thiosulfate VS (indicator: 1 mL of starch TS). Perform a blank determination in the same manner, and make any necessary correction (not more than 0.0005%).

Propanol, iso See 2-propanol.

Propantheline bromide $C_{23}H_{30}BrNO_3$ [Same as the namesake monograph]

Propionic acid CH_3CH_2COOH Colorless liquid.
Purity—Clarity and color of solution—Dissolve 1 g of propionic acid in 20 mL of ethanol (95): the solution is clear and colorless.
Specific gravity d_{20}^{20}: 0.998 - 1.004
Distilling range: 139 - 143°C, not less than 95 vol%.

Propylamine, iso $(CH_3)_2CHNH_2$ Colorless liquid, having a characteristic, amine-like odor. Miscible with water, with ethanol (95) and with diethyl ether.
Refractive index n_D^{20}: 1.374 - 1.376
Specific gravity d_{20}^{20}: 0.685 - 0.690
Distilling range: 31 - 33°C, not less than 95 vol%.

Propyl benzoate $C_6H_5COOC_3H_7$ Clear, colorless liquid, having a characteristic odor.
Refractive index n_D^{20}: 1.498 - 1.503
Specific gravity d_{20}^{20}: 1.022 - 1.027

Propylene carbonate $C_4H_6O_3$ Colorless liquid.
Boiling point: 240 - 242°C
Water: less than 0.1%

Propylene carbonate for water determination See the Water Determination under the General Tests, Processes and Apparatus.

Propylene glycol $CH_3CH(OH)CH_2OH$ [K 8837, Special class]

Propylene glycol cefatrizine $C_{18}H_{18}N_6O_5S_2.C_3H_8O_2$ [Same as the namesake monograph]

Propylether, iso $(CH_3)_2CHOCH(CH_3)_2$ Clear, colorless liquid, having a characteristic odor. Not miscible with water.
Refractive index n_D^{20}: 1.368 - 1.369
Specific gravity d_4^{20}: 0.723 - 0.725

Propyl parahydroxybenzoate
$HOC_6H_4COOCH_2CH_2CH_3$ [Same as the namesake monograph in Part II]

Propylthiouracil for assay $C_7H_{10}N_2OS$ [Same as the monograph Propylthiouracil. When dried, it contains not less than 99.0% of propylthiouracil ($C_7H_{10}N_2OS$).]

Prostaglandin A_1 $C_{20}H_{32}O_4$ White crystals or crystalline powder. Very soluble in ethanol (95) and in ethyl acetate, and very slightly soluble in water.
Purity Related substances—Dissolve 5 mg of prostaglandin A_1 in 10 mL of ethanol (95), and use this solution as the sample solution. Pipet 3 mL of the sample solution, add ethanol (95) 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 under the Liquid Chromatography according to the following operating conditions. Determine areas of all peaks of both solutions by the automatic integration method: the total area of the peaks other than the peak of prostaglandin A_1 from the sample solution is not larger than the peak area of prostaglandin A_1 from the standard solution.
Operating conditions
Detector, column, column temperature, mobile phase, flow rate, and selection of column: Proceed the operating conditions in the Assay of Alprostadil Alfadex.
Detection sensitivity: Adjust the detection sensitivity so that the peak height of prostaglandin A_1 obtained from 10 μL of the standard solution is 5 to 10% of the full scale.
Time span of measurement: About twice as long as the retention time of prostaglandin A_1 after the solvent peak.

Puerarin for thin-layer chromatography $C_{21}H_{20}O_9$ White crystalline powder. Freely soluble in methanol, and practically insoluble in diethyl ether.
Melting point: about 188°C (with decomposition).
Purity Related substances—Dissolve 1.0 mg of puerarin for thin-layer chromatography in exactly 1 mL of methanol. Perform the test with 2 μL of this solution as directed in the Identification under Pueraria Root: any spot other than the principal spot at the *Rf* value of about 0.4 does not appear.

Purified hydrochloric acid See hydrochloric acid, purified.

Purified methanol See methanol, purified.

Purified sulfuric acid See sulfuric acid, purified.

Purified water [Same as the namesake monograph in Part II]

Purified water for ammonium limit test To 1500 mL of purified water add cautiously 4.5 mL of sulfuric acid, distil using a hard glass distiller, discard the first distillate, and use the remaining distillate as ammonium-free purified water.
Purity—Mix 40 mL of purified water for ammonium limit test with 6.0 mL of phenol-sodium pentacyanonitrosylferrate (III) TS. Add 4.0 mL of sodium hypochlorite-sodium hydroxide TS, mix, and allow to stand for 60 minutes. Perform the test with this solution as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank: absorbance at the wavelength of 640 nm is not more than 0.010.

Pyrazole $C_3H_4N_2$ White to pale yellow crystals or crystalline powder.
Melting point: 67 - 71°C

Pyridine C_5H_5N [K 8777, Speial class]

Pyridine-acetic acid TS Dilute 20 mL of pyridine with sufficient diluted acetic acid (100) (1 in 25) to make 100 mL. Prepare before use.

Pyridine, dehydrated C_5H_5N To 100 mL of pyridine add 10 g of sodium hydroxide, and allow to stand for 24 hours. Decant the supernatant liquid, and distill.

Pyridine for Karl Fischer method See the Water Determination under the General Tests, Processes and Apparatus.

Pyridine-pyrazolone TS Dissolve, with thorough shaking, 0.1 g of 3-methyl-1-phenyl-5-pyrazolone in 100 mL of water by heating between 65°C and 70°C, and cool below

30°C. Mix this solution with a solution prepared by dissolving 0.02 g of bis-(1-phenyl-3-methyl-5-pyrazolone) in 20 mL of pyridine. Prepare before use.

Pyridoxine hydrochloride $C_8H_{11}NO_3.HCl$ [Same as the namesake monograph]

1-(2-Pyridylazo)-2-naphthol $C_{15}H_{11}N_3O$ Orange-yellow or orange-red powder.

Absorbance—Dissolve 0.025 g of 1-(2-pyridylazo)-2-naphthol in methanol to make exactly 100 mL. Pipet 2.0 mL of this solution, and add methanol to make exactly 50 mL. Perform the test with this solution as directed under the Ultraviolet-visible Spectrophotometry, using methanol as the blank: absorbance at the wavelength of 470 nm is not less than 0.55.

Melting point: 137 - 140°C

Purity Clarity and color of solution—Dissolve 0.025 g of 1-(2-pyridylazo)-2-naphthol in 100 mL of methanol: the solution is clear and orange-yellow.

Residue on ignition: not more than 1.0%.

Sensitivity—On adding 50 mL of water, 30 mL of methanol and 10 mL of acetic acid-sodium acetate buffer solution, pH 5.5, to 0.2 mL of a solution of 1-(2-pyridylazo)-2-naphthol in methanol (1 in 4000), the solution is yellow in color. Add 1 drop of a solution of copper (II) chloride dihydrate (1 in 600) to this solution: the solution is red-purple in color. Add a subsequent 1 drop of diluted 0.1 mol/L disodium dihydrogen ethylenediamine tetraacetate TS (1 in 10): the color of the solution changes to yellow again.

1-(4-Pyridyl)pyridinium chloride hydrochloride $C_{10}H_9ClN_2.HCl$ White to yellowish white, crystalline powder. Very soluble in water, very slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

Melting point: 154 - 156°C

Pyrogallol $C_6H_3(OH)_3$ [K 8780, Special class]

L-Pyroglutamylglycyl-L-arginine-*p*-nitroanilide TS Dissolve 0.025 g of L-pyroglutamylglycyl-L-arginine-*p*-nitroanilide hydrochloride and 0.04 g of D-Mannitol in 2 to 3 mL of water, lyophilyze, and dissolve in 16.7 mL of water. To 1 volume of this solution add 9 volumes of water before use.

L-Pyroglutamylglycyl-L-arginine-*p*-nitroaniline hydrochloride $C_{19}H_{26}N_8O_6.HCl$ White to light powder. Freely soluble in water, in methanol and in acetic acid (100).

Absorbance $E^{1\%}_{1cm}$ (316 nm): 242 - 268 (2 mg, water, 100 mL).

Optical rotation $[\alpha]_D^{25}$: −51 - −56° [0.1 g, diluted acetic acid (100) (1 in 2), 10 mL, 100 mm].

Purity Related substances—Dissolve 0.05 g of L-pyroglutamylglycyl-L-arginine-*p*-nitroaniline hydrochloride in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water, pyridine and acetic acid (100) (15:12:10:3) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

L-Pyroglutamylglycyl-L-arginine-4-nitroaniline hydrochloride TS Dissolve 0.025 g of L-pyroglutamylglycyl-L-arginine-4-nitroaniline hydrochloride and 0.04 g of D-Mannitol in 2 to 3 mL of water, lyophilize, and add 16.7 mL of water to dissolve. To 1 volume of this solution add 9 volumes of water before use.

Pyrole C_4H_5N Clear, colorless liquid, having a characteristic oder. Soluble in ethanol (95) and in diethyl ether, and practically insoluble in water.

Specific gravity d_{20}^{20}: 0.965 - 0.975

Pyrophosphate buffer solution, pH 9.0 Dissolve 3.3 g of potassium pyrophosphate, 15 mg of dithiothreitol and 40 mg of disodium dihydrogen ethylenediamine tetraacetate dihydrate in 70 mL of water, adjust the pH with a solution of citric acid monohydrate (21 in 100) to exactly 9.0, and add water to make 100 mL.

0.3 mol/L Pyrophosphate buffer solution, pH 9.0 Dissolve 0.83 g of potassium pyrophosphate in 40 mL of water, adjust the pH with 1 mol/L hydrochloric acid VS to 9.0, and add water to make 50 mL. Adjust the temperature to 22 ± 2°C before use.

Quinhydrone $C_6H_4(OH)_2.C_6H_4O_2$ [K 8281: 1961, Special class]

Quinidine sulfate $(C_{20}H_{24}N_2O_2)_2.H_2SO_4.2H_2O$ [Same as the namesake monograph]

Quinine sulfate $(C_{20}H_{21}N_2O_2)_2.H_2SO_4.2H_2O$ [Same as the namesake monograph]

Quinoline C_9H_7N [K 8279, Special class]

Quinoline TS Mix 50 mL of quinoline with 300 mL of diluted hydrochloric acid (1 in 6), previously heated, cool, and filter if necessary.

8-Quinolinol C_9H_7NO [K 8775, Special class]

Raney nickel catalyst Grayish black powder. An alloy containing 40 to 50% of nickel and 50 to 60% of aluminum.

Red litmus paper See litmus paper, red.

Reduced iron Fe [K 8262: 1980, Special class]

Reinecke salt See reinecke salt monohydrate.

Reinecke salt monohydrate $NH_4[Cr(NH_3)_2(SCN)_4].H_2O$ [K 8926, Special class]

Reinecke salt TS To 20 mL of water add 0.5 g of Reinecke salt monohydrate, shake frequently for 1 hour, then filter. Use within 48 hours.

Resazurin $C_{12}H_6NNaO_4$ Brownish purple powder. It dissolves in water and the solution is purple in color.

Residue on ignition: not less than 28.5% (1 g).

Resibufogenin for component determination $C_{24}H_{32}O_4.xH_2O$ Odorless white crystalline powder.

Absorbance $E^{1\%}_{1cm}$ (300 nm): 131 - 145 (0.01 g, methanol, 250 mL), dried in a desiccator (silica gel) for 24 hours.

Purity Related substances—Weigh accurately 0.04 g of resibufogenin for component determination and proceed as directed in the Purity under bufalin for component determination.

Content: not less than 98.0%. Component determination—Weigh accurately about 0.01 g of resibufogenin for component determination, previously dried in a desiccator (silica gel) for 24 hours, add methanol to make exactly 10 mL, and use this solution as the sample solution. Perform the test with 20 μL of this solution as directed under the Liquid Chromatography according to the following conditions. Measure each peak area by the automatic integration method, and calculate the amount of resibufogenin by the area percentage method.

Operating conditions

Detector: Ultraviolet absorption photometer (wavelength: 300 nm).

Column: A stainless steel column about 4 to 6 mm in inside diameter and 15 to 30 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 to 10 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: A mixture of water and acetonitrile (1:1).

Selection of column: Dissolve 0.01 g each of bufalin for component determination, cinobufagin for component determination and resibufogenin for component determination in methanol to make 200 mL. Perform the test with 20 μL of this solution according to the above operating conditions, and calculate the resolution. Use a column giving elution of bufalin, cinobufagin and resibufogenin in this odor, and clearly dividing each peak.

Detection sensitivity: Pipet 1 mL of sample solution, add methanol to make exactly 100 mL, and use this solution as the standard solution (1). Pipet 1 mL of the standard solution (1), add methanol to make exactly 20 mL, and use this solution as the standard solution (2). Adjust the detection sensitivity so that the peak area of resibufogenin obtained from 20 μL of standard solution (2) can be measured by the automatic integration method and the peak height of resibufogenin from 20 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 resibufogenin after the peak of solvent.

Resorcin See resorcinol.

Resorcinol $C_6H_4(OH)_2$ [K 9032, Resorcinol, Special class]

Resorcinol sulfuric acid TS Dissolve 0.1 g of resorcinol in 10 mL of diluted sulfuric acid (1 in 10).

Resorcinol TS Dissolve 0.1 g of resorcinol in 10 mL of hydrochloric acid. Prepare before use.

Resorcin sulfuric acid TS See resorcinol sulfuric acid TS.

Resorcin TS See resorcinol TS.

Riboflavin $C_{17}H_{20}N_4O_6$ [Same as the namesake monograph]

Riboflavin sodium phosphate $C_{17}H_{20}N_4NaO_9P$ [Same as the namesake monograph]

Saccharated pepsin [Same as the namesake monograph in Part II]

Saikosaponin a for thin-layer chromatography $C_{42}H_{68}O_{13}$ Colorless or white, odorless powder. Freely soluble in methanol and in ethanol (95), and practically insoluble in chloroform and in diethyl ether.

Melting point: 225 - 232°C (with decomposition).

Purity Related substances—Dissolve 1.0 mg of saikosaponin a for thin-layer chromatography in exactly 1 mL of methanol, and perform the test with 10 μL of this solution as directed in the Identification (2) under Bupleurum Root: any spot other than the principal spot at the *Rf* value of about 0.4 does not appear.

Salicylaldazine $C_{14}H_{12}N_2O_2$ Dissolve 0.30 g of hydrazinium sulfate in 5 mL of water. To this solution add 1 mL of acetic acid (100) and 2 mL of a freshly prepared solution of salicylaldehyde in 2-propanol (1 in 5), shake well, and allow to stand until a yellow precipitate is produced. Extract with two 15 mL portions of dichloromethane, to the combined dichloromethane extracts add 5 g of anhydrous sodium sulfate, shake, decant or filter, and evaporate the dichloromethane in the supernatant liquid or filtrate. Dissolve the residue in a warmed mixture of toluene and methanol (3:2), and cool. Filter the crystals produced, and dry in a desiccator (in vacuum, silica gel) for 24 hours. It is a yellow, crystalline powder.

Melting point: 213 - 219°C

Purity—Dissolve 0.09 g of salicylaldazine in toluene to make exactly 100 mL. Pipet 1 mL of this solution, add toluene to make exactly 100 mL, and perform the test with this solution as directed in the Purity (6) under Povidone: any spot other than the principal spot does not appear.

Salicylaldehyde HOC_6H_4CHO [K 8390, Special class]

Salicylamide $C_7H_7NO_2$ White crystals or crystalline powder, and it is odorless and tasteless. Very soluble in *N,N*-dimethylformamide, freely soluble in ethanol (95), soluble in propylene glycol, sparingly soluble in diethyl ether, and slightly soluble in water and in chloroform. It dissolves in sodium hydroxide TS.

Melting point: 139 - 143°C

Purity Ammonium—Shake 1.0 g of salicylamide with 40 mL of water, and filter through filter paper previously washed well with water. Discard the first 10 mL of the filtrate, transfer the subsequent 20 mL to a Nessler tube, and add water to make 30 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: transfer 2.5 mL of Standard Ammonium Solution to a Nessler tube, and add water to make 30 mL.

Loss on drying: not more than 0.5% (1 g, silica gel, 4 hours).

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

Content: not less than 98.5%. Assay—Weigh accurately about 0.2 g of salicylamide, previously dried, dissolve in 70 mL of *N,N*-dimethylformamide, and titrate with 0.1 mol/L tetramethylammonium hydroxide VS (potentiometric titration). Separately, perform a blank determination with a solution of 70 mL of *N,N*-dimethylformamide in 15 mL of water, and make any necessary correction.

Each mL of 0.1 mol/L tetramethylammonium hydroxide VS = 13.714 mg of $C_7H_7NO_2$

Salicylic acid HOC_6H_4COOH [K 8392, Special class]

Salicylic acid for assay HOC_6H_4COOH [K 8392, Special class]

Salicylic acid TS Dissolve 0.1 g of salicylic acid in 10 mL of sulfuric acid. Prepare before use.

Santonin $C_{15}H_{18}O_3$ [Same as the namesake monograph]

Santonin for assay [Same as the monograph Santonin. It contains not less than 99.0% of santonin ($C_{15}H_{18}O_3$).]

Schisandrin for thin-layer chromatography $C_{24}H_{32}O_7$ White crystals for crystalline powder. Freely soluble in methanol and diethyl ether, and practically insoluble in water.

Melting point: 130 - 135°C

Purity Related substances—Dissolve 1.0 mg of schisandrin for thin-layer chromatography in exactly 1 mL of methanol. Perform the test with 5 μL of this solution as directed in the Identification under Schisandra Fruit: any spot other than the principal spot at the *R*f value of about 0.4 does not appear.

Scopolamine hydrobromide $C_{17}H_{21}NO_4.HBr.3H_2O$ [Same as the namesake monograph]

Scopolamine hydrobromide for thin-layer chromatography [Same as the monograph Scopolamine Hydrobromide. Proceed as directed in the Identification (3) under Opium Alkaloids and Atropine Injection: any spot other than the principal spot at the *R*f value of about 0.7 does not appear.

Sea sand [K 8222, Special class]

Selenious acid H_2SeO_3 [K 8035, Special class]

Selenious acid-sulfuric acid TS Dissolve 0.05 g of selenious acid in 10 mL of sulfuric acid.

Selenium Se [K 8598, Special class]

Selenium dioxide SeO_2 [K 8706, Special class]

Semicarbazide acetate TS Place 2.5 g of semicarbazide hydrochloride, 2.5 g of anhydrous sodium acetate and 30 mL of methanol in a flask, heat on a water bath for 2 hours, cool to 20°C, and filter. To the filtrate add methanol to make 100 mL. Preserve in a cold place. Do not use the solution showing a yellow color.

Semicarbazide hydrochloride $H_2NNHCONH_2.HCl$ [K 8195: 1992, Special class]

Sennoside A for component determination Use sennoside A for thin-layer chromatography meeting the following additional specifications.

Absorbance $E^{1\%}_{1cm}$ (270 nm): 211 - 226 [0.01 g dried in a desiccator (in vacuum at a pressure not exceeding 0.67 kPa, phosphorus (V) toxide) for not less than 12 hours, diluted sodium bicarbonate solution (1 in 100), 500 mL]

Purity Related substances—Dissolve 5.0 mg of sennoside A for component determination in 50 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 25 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 measure each peak area from these solutions by the automatic integration method: the total peak area other than sennoside A obtained from the sample solution is not larger than peak area of sennoside A from the standard solution (1).

Operating conditions

Proceed the operating conditions in the Component determination under Senna Leaf 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 detection sensitivity so that the peak area of sennoside A obtained from 10 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of sennoside A from 10 μL of the standard solution (1) is about 20% of the full scale.

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

Sennoside A for thin-layer chromatography $C_{42}H_{38}O_{20}$ Yellow crystalline powder. Insoluble in water, in chloroform and in diethyl ether, and practically insoluble in methanol and in acetone.

Melting point: 200 - 240°C (with decomposition).

Purity Related substances—Dissolve 1.0 mg of sennoside A for thin-layer chromatography in exactly 4 mL of a mixture of tetrahydrofuran and water (7:3), and perform the test with 80 μL of this solution as directed in the identification under Rhubarb: any spot other than the principal spot at the *R*f value of about 0.3 does not appear.

Sennoside B for component determination $C_{42}H_{38}O_{20}$ Yellow crystalline powder. Insoluble in water and in diethyl ether, and practically insoluble in methanol and in acetone.

Melting point: 180 - 186°C (with decomposition).

Absorbance $E^{1\%}_{1cm}$ (270 nm): 210 - 225 [0.01 g dried in a desiccator (in vacuum at a pressure not exceeding 0.67 kPa, phosphorus (V) toxide) for not less than 12 hours, diluted sodium bicarbonate solution (1 in 100), 500 mL]

Purity Related substances—(1) Dissolve 1.0 mg of Sennoside B for component determination in exactly 4 mL of a mixture of tetrahydrofuran and water (7:3), and perform the test as directed under the Thin-layer Chromatography with this solution. Spot 80 μL of this solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, 1-propanol, water and formic acid (7:7:4:2) to a distance of about 15 cm, and air-dry the plate. Examine under the ultraviolet light (main wavelength: 365 nm): any spot other than the principal spot as the *R*f value of about 0.5 does not appear.

(2) Dissolve 5.0 mg of sennoside B for component determination in 50 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 25 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 measure each peak area from these solutions by the automatic integration method: the total peak area other than sennoside B obtained from the sample solution is not larger than peak area of sennoside B from the standard solution (1).

Operating conditions

Proceed the operating conditions in the Component determination under Senna Leaf except detection sensitivity and time span of measurement.