in chloroform, and very slightly soluble in water and in ethanol (95).

Melting point: 103 - 106°C (dried substance) (with decomposition).

Loss on drying: not more than 30% (0.1 g, in vacuum, silica gel, constant mass).

Benzyl alcohol $C_6H_5CH_2OH$ [K 8854, Special class]

Benzyl benzoate $C_6H_5COOCH_2C_6H_5$ [K 8079, Special class]

Benzyl parahydroxybenzoate $C_{14}H_{12}O_3$ White, odorless, fine crystals or crystalline powder. Freely soluble in ethanol (95), in acetone and in diethyl ether, and very slightly soluble in water.

Melting point: 109 - 112°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
= 228.25 mg of $C_{14}H_{12}O_3$

Benzylpenicillin potassium $C_{16}H_{17}KN_2O_4S$ [Same as the monograph Benzylpenicillin Potassium]

Benzyl *p*-hydroxybenzoate See benzyl parahydroxybenzoate.

***p*-Benzylphenol** $C_6H_5CH_2C_6H_4OH$ White to pale yellowish white crystals or crystalline powder.

Melting point: 80 - 85°C

Berberine chloride $C_{20}H_{18}ClNO_4.xH_2O$ [Same as the namesake monograph]

Berberine chloride for component determination Use berberine chloride for thin-layer chromatography meeting the following additional specifications.

Absorbance $E^{1\%}_{1cm}$ (345nm): 640 - 700 (1 mg, diluted ethanol, 50 mL). Allow to stand for 1 hour in a vessel fully moistened with water kept filling for not less than 12 hours, and dry in a desiccator (silica gel, 60°C) for 1 hour.

Purity Related substances—Dissolve 0.010 g of berberine chloride for component determination in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of this solution, add methanol to make exactly 100 mL, and use this solution as the standard solution (1). Perform the test with 1 mL each of the sample solution and the standard solution (1) as directed under the Liquid Chromatography according to the following conditions, measure the peak areas obtained from the sample solution and the standard solution (1) by the automatic integration method: the total peak areas other than berberine from the sample solution is not larger than the peak area of berberine from the standard solution (1).

Operatining conditions

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

Detection sensitivity: Pipet 1 mL of the standard solution (1), add methanol to make exactly 20 mL, and use this solution as standard solution (2). Adjust the detection sensitivity so that the peak area of berberine obtained from 20 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of berberine from the standard solution (1) is about 20% of the full scale.

Time span of measurement: About twice as long as the retention time of berberine after the solvent peak.

Berberine chloride for thin-layer chromatography [Same as the monograph Berberine Chloride. Use the berberine chloride meeting the following additional specifications.]

Purity Related substances—Dissolve 0.010 g of berberine chloride for thin-layer chromatography 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 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 (2) under Phellodendron Bark: any spot other than the principal spot from the sample solution is not more intense than the spot from the standard solution.

Bergenin for thin-layer chromatography $C_{14}H_{16}O_9 \cdot xH_2O$ White crystals or crystalline powder. Freely soluble in ethanol (95), soluble in water, and insoluble in diethyl ether.

Melting point: 131 - 133°C, 234 - 236°C (double melting points).

Purity Related substances—Dissolve 1.0 mg of bergenin for thin-layer chromatography in exactly 1 mL of methanol. Perform the test with 20 μL of this solution as directed in the Identification under Mallotus Bark: any spot other than the principal spot at the *R*f value of about 0.5 does not appear.

Betanidine sulfate for assay $(C_{10}H_{15}N_3)_2.H_2SO_4$ [Same as the monograph Betanidine Sulfate. Calculated on the dried basis, it contains not less than 99.0% of betanidine sulfate $(C_{10}H_{15}N_3)_2.H_2SO_4$]

BGLB Dissolve 10 g of peptone and 10 g of lactose monohydrate in 500 mL of water, add 200 mL of fresh ox bile or a solution prepared by dissolving 20 g of dried ox bile powder in 200 mL of water and adjusted the pH to between 7.0 and 7.5, then add water to make 975 mL, and again adjust to pH 7.4. Then add 13.3 mL of a solution of brilliant green (1 in 1000) and water to make 1000 mL in total volume, and filter through absorbent cotton. Dispense 10 mL portions of the filtrate into tubes for fermentation, and sterilize by autoclaving at 121°C for not more than 20 minutes, then cool quickly, or sterilize fractionally on each of three successive days for 30 minutes at 100°C.

α-BHC (α-Hexachlorocyclohexane) $C_6H_6Cl_6$

Melting point: 157 - 159°C

Purity Related substances—Dissolve 0.010 g of α-BHC in 5 mL of acetone for purity of crude drug, and add hexane for purity of crude drug to make exactly 100 mL. Pipet 1 mL of this solution, add hexane for purity of crude drug to make exactly 100 mL, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add hexane for purity of crude drug to make exactly 100 mL, and use this solution as the standard solution (1). Perform the test with 1 μL each of the sample solution and the standard solution (1) as directed in the Gas 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 α-BHC from the sample solution is not larger than the peak area of α-BHC from the standard solution (1).

Operating conditions

Proceed the operating conditions in the Purity (3) under Powdered Ginseng except detection sensitivity and time span of measurement.

Detection sensitivity: Pipet 1 mL of the standard solution (1), add hexane for purity of crude drug to make 20 mL, and use this solution as standard solution (2). Adjust the detection sensitivity so that the peak area of α-BHC obtained from 1 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of α-BHC from 1 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 α-BHC after the peak of solvent.

β-BHC (β-Hexachlorocyclohexane) $C_6H_6Cl_6$

Melting point: 308 - 310°C

Purity Related substances—Proceed as directed in the Purity under α-BHC using the following standard solution (1).

Standard solution (1): Pipet 2 mL of the sample solution, and add hexane for purity of crude drug to make exactly 100 mL.

γ-BHC (γ-Hexachlorocyclohexane) $C_6H_6Cl_6$

Melting point: 112 - 114°C

Purity Related substances—Proceed as directed in the Purity under α-BHC.

δ-BHC (δ-Hexachlorocyclohexane) $C_6H_6Cl_6$

Melting point: 137 - 140°C

Purity Related substances—Proceed as directed in the Purity under α-BHC using the following standard solution (1).

Standard solution (1): Pipet 5 mL of the sample solution, and add hexane for purity of crude drug to make exactly 100 mL.

2-(4-Biphenylyl)propionic acid $C_{15}H_{14}O_2$ Light yellowish white powder.

Melting point: 145 - 148°C

Purity—Dissolve 1 mg of 2-(4-biphenylyl) propionic acid in a mixture of water and acetonitrile (11:9) to make 50 mL. Perform the test with 20 μL of this solution as directed under the Liquid Chromatography according to the operating conditions of the Related substances in the Purity (3) under Flurbiprofen. Determine each peak area of the solution in about twice as long as the retention time of the main peak by the automatic integration method, and calculate the amount of 2-(4-biphenylyl)propionic acid by the area percentage method: it is not less than 98.0%.

Content: not less than 98.0%. Assay—Weigh accurately about 0.5 g of 2-(4-biphenilyl)propionic acid, previously dried in vacuum over silica gel for 4 hours, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 22.627 mg of $C_{15}H_{14}O_2$

2,2′-Bipyridyl $C_{10}H_8N_2$ [K 8486, Special class]

***N,N′*-Bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide** $C_{16}H_{20}I_3N_3O_8$ White crystalline powder.

Identification—(1) Heat 0.1 g of *N,N′*-bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide over free flame: a purple colored gas evolves.

(2) Determine the infrared absorption spectrum of *N,N′*-bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide according to the potassium bromide disk method under the Infrared Spectrophotometry: it exhibits absorption at the wave numbers of about 3390 cm^{-1}, 3233 cm^{-1}, 2882 cm^{-1}, 1637 cm^{-1}, 1540 cm^{-1}, 1356 cm^{-1} and 1053 cm^{-1}.

Purity—Dissolve 0.10 g of *N,N′*-bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide in 10 mL of water, and use this solution as the sample solution. Pipet 1 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions. Determine each peak area of both solutions by automatic integration method: the total peak area of peaks other than the peak of *N,N′*-bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide obtained from the sample solution is not more than 3 times of the peak area of *N,N′*-bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5 - hydroxyacetylamino - 2,4,6 - triiodoisophthalamide obtained from the standard solution.

Operating conditions

Proceed the operating conditions in the Purity (6) under Iopamidol.

System suitability

Proceed the system suitability in the Purity (6) under Iopamidol.

Bismuth nitrate See bismuth nitrate pentahydrate.

Bismuth nitrate pentahydrate $Bi(NO_3)_3.5H_2O$ [K 8566, Special class]

Bismuth nitrate-potassium iodide TS Dissolve 0.35 g of bismuth nitrate pentahydrate in 4 mL of acetic acid (100) and 16 mL of water (solution A). Dissolve 8 g of potassium iodide in 20 mL of water (solution B). To 20 mL of a mixture of solution A and solution B (1:1) add 80 mL of dilute sulfuric acid and 0.2 mL of hydrogen peroxide (30). Prepare before use.

Bismuth nitrate TS Dissolve 5.0 g of bismuth nitrate pentahydrate in acetic acid (100) to make 100 mL.

Bismuth potassium iodide TS Dissolve 10 g of L-tartaric acid in 40 mL of water, add 0.85 g of bismuth subnitrate, shake for 1 hour, add 20 mL of a solution of potassium iodide (2 in 5), shake thoroughly, allow to stand for 24 hours, and filter (solution A). Separately, dissolve 10 g of L-tartaric acid in 50 mL of water, add 5 mL of solution A, and preserve in light-resistant, glass-stoppered bottles.

Bismuth sodium trioxide $NaBiO_3$ [K 8770, Special class]

Bismuth subnitrate [Same as the namesake monograph]

Bismuth subnitrate TS Dissolve 10 g of L-tartaric acid in 40 mL of water, add 0.85 g of bismuth subnitrate, stir for 1 hour, then add 20 mL of a solution of potassium iodide (2 in

5), and shake well. After standing for 24 hours, filter, and preserve the filtrate in a light-resistant bottle.

Bismuth sulfite indicator Prepared for microbial test.

Bis-trimethyl silyl acetamide $CH_3CON[Si(CH_3)_3]_2$ Colorless liquid.

Refractive index n_D^{20}: 1.414 - 1.418

Specific gravity d_{20}^{20}: 0.825 - 0.835

Boiling point: 71 - 73°C

Bis-(1-phenyl-3-methyl-5-pyrazolone) $C_{20}H_{18}B_4O_2$ White to pale yellow crystals or crystalline powder. It dissolves in mineral acids and in alkali hydroxides, and it does not dissolve in water, in ammonia TS, or in organic solvents.

Melting point: not below 300°C.

Residue on ignition: not more than 0.1%.

Nitrogen content: 15.5 - 16.5%

Blue litmus paper See litmus paper, blue.

Blue tetrazolium $C_{40}H_{32}Cl_2N_8O_2$ 3,3'-Dianisole-bis-[4,4'-(3,5-diphenyl) tetrazolium chloride] Light yellow crystals. Freely soluble in methanol, in ethanol (95) and in chloroform, slightly soluble in water, and practically insoluble in acetone and in ether.

Melting point: about 245°C (with decomposition).

Absorbance $E_{1\,cm}^{1\%}$ (252 nm): not less than 826 (methanol).

Blue tetrazolium TS, alkaline To 1 volume of a solution of blue tetrazolium in methanol (1 in 200) add 3 volumes of a solution of sodium hydroxide in methanol (3 in 25). Prepare before use.

Borax See sodium tetraborate.

Boric acid H_3BO_3 [K 8863, Special class]

Boric acid-methanol buffer solution Weigh exactly 2.1 g of boric acid, dissolve in 28 mL of sodium hydroxide TS, and dilute with water to exactly 100 mL. Mix equal volumes of this solution and methanol, and shake.

Boric acid-potassium chloride-sodium hydroxide buffer solution, pH 9.0 To 50 mL of 0.2 mol/L boric acid-0.2 mol/L potassium chloride TS for buffer solution add 21.30 mL of 0.2 mol/L sodium hydroxide VS and water to make 200 mL.

Boric acid-potassium chloride-sodium hydroxide buffer solution, pH 9.2 To 50 mL of 0.2 mol/L boric acid-0.2 mol/L potassium chloride TS for buffer solution add 26.70 mL of 0.2 mol/L sodium hydroxide VS and water to make 200 mL.

Boric acid-potassium chloride-sodium hydroxide buffer solution, pH 9.6 To 50 mL of 0.2 mol/L boric acid-0.2 mol/L potassium chloride TS for buffer solution add 36.85 mL of 0.2 mol/L sodium hydroxide VS and water to make 200 mL.

Boric acid-potassium chloride-sodium hydroxide buffer solution, pH 10.0 To 50 mL of 0.2 mol/L boric acid-0.2 mol/L potassium chloride TS for buffer solution add 43.90 mL of 0.2 mol/L sodium hydroxide VS and water to make 200 mL.

Boric acid-sodium hydroxide buffer solution, pH 8.4 Dissolve 24.736 g of boric acid in 0.1 mol/L sodium hydroxide VS to make exactly 1000 mL.

0.2 mol/L Boric acid-0.2 mol/L potassium chloride TS for buffer solution Dissolve 12.376 g of bodic acid and 14.911 g of potassium chloride in water to make 1000 mL.

Boron trifluoride BF_3 Colorless gas, having an irritating odor.

Melting point: −127.1°C

Boiling point: −100.3°C

Boron trifluoride-methanol TS A solution containing 14 w/v% of boron trifluoride (BF_3: 67.81) in methanol.

Bovine serum albumin Obtained from cattle serum as Cohn's fifth fraction. Contains not less than 95% of albumin.

Bovine serum albumin for test of ulinastatin White crystalline powder obtained from bovine serum by a purification method which does not denature albumin and other serum proteins. It contains not less than 99% of albumin.

Bovine serum albumin TS for secretin Dissolve 0.1 g of bovine serum albumin, 0.1 g of L-cysteine hydrochloride monohydrate, 0.8 g of L-alanine, 0.01 g of citric acid monohydrate, 0.14 g of disodium hydrogenphosphate 12-water and 0.45 g of sodium chloride in 100 mL of water for injection.

Bovine serum albumin TS for Secretin Reference Standard Dissolve 0.1 g of bovine serum albumin, 0.8 g of L-alanine, 0.01 g of citric acid monohydrate, 0.14 g of disodium hydrogenphosphate 12-water and 0.45 g of sodium chloride in 100 mL of water for injection.

Bovine serum albumin-isotonic sodium chloride solution Dissolve 0.1 g of bovine serum albumin in isotonic sodium chloride solution to make 100 mL. Prepare before use.

Bradykinin $C_{50}H_{73}N_{15}O_{11}$ A white powder. Freely soluble in water and in acetic acid (31), and practically insoluble in diethyl ether.

Optical rotation $[\alpha]_D^{20}$: −80 - −90° (0.015 g, water, 5 mL, 100 mm).

Purity Related substances—Dissolve 2 mg of bradykinin in 0.2 mL of water, and use this solution as the sample solution. Perform the test with the sample solution as directed under the Thin-layer Chromatography. Spot 5 μL of the sample solution on a plate of cellulose for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water, pyridine and acetic acid (31) (15:12:10:3) to a distance of about 10 cm, and dry the plate at 60°C. Spray evenly a solution of ninhydrin in 1-butanol (1 in 1000) on the plate, and heat at 60°C for 30 to 60 minutes: any spot other than the principal spot arisen from bradykinin does not appear.

Brilliant green $C_{27}H_{34}N_2O_4S$ Fine, glistening, yellow crystals. It dissolves in water and in ethanol (95). The wavelength of absorption maximum: 623 nm.

Bromine Br [K 8529, Special class]

Bromine-acetic acid TS Dissolve 10 g of sodium acetate trihydrate in acetic acid (100) to make 100 mL, add 5 mL of bromine, and shake. Preserve in light-resistant containers, preferably in a cold place.

Bromine-carbon tetrachloride TS To 0.1 g of bromine add carbon tetrachloride to make 100 mL, and dilute a 2 mL portion of this solution with carbon tetrachloride to make 100 mL. Prepare before use.

Bromine-cyclohexane TS Dissolve 0.1 g of bromine in cyclohexane to make 100 mL. To 2 mL of this solution add cyclohexane to make 10 mL. Prepare before use.

Bromine-sodium hydroxide TS To 100 mL of a solution of sodium hydroxide (3 in 100) add 0.2 mL of bromine. Prepare before use.

Bromine TS Prepare by saturating water with bromine as follows: Transfer 2 to 3 mL of bromine to a glass-stoppered bottle, the stopper of which should be lubricated with petrolatum, add 100 mL of cold water, insert the stopper, and shake. Preserve in light-resistant containers, preferably in a cold place.

Bromocresol green $C_{21}H_{14}Br_4O_5S$ [K 8840, Special class]

Bromocresol green-crystal violet TS Dissolve 0.3 g of bromocresol green and 0.075 g of crystal violet in 2 mL of ethanol (95), and dilute with acetone to make 100 mL.

Bromocresol green-methyl red TS Dissolve 0.15 g of bromocresol green and 0.1 g of methyl red in 180 mL of ethanol (99.5), and add water to make 200 mL.

Bromocresol green-methylrosaniline chloride TS See bromocresol green-crystal violet TS.

Bromocresol green-sodium hydroxide-acetic acid-sodium acetate TS To 0.25 g of bromocresol green add 15 mL of water and 5 mL of dilute sodium hydroxide TS, then add a small quantity of acetic acid-sodium acetate buffer solution, pH 4.5, dissolve while shaking, and add acetic acid-sodium acetate buffer solution, pH 4.5, to make 500 mL. Wash 250 mL of the solution with two 100 mL portions of dichloromethane. Filter if necessary.

Bromocresol green-sodium hydroxide TS Triturate 0.2 g of bromocresol green with 2.8 mL of 0.1 mol/L sodium hydroxide VS in a mortar, add water to make 200 mL, and filter if necessary.

Bromocresol green TS Dissolve 0.05 g of bromocresol green in 100 mL of ethanol (95), and filter if necessary.

Bromocresol purple $C_{21}H_{16}Br_2O_5S$ [K 8841, Special class]

Bromocresol purple-dibasic potassium phosphate-citric acid TS See bromocresol purple-dipotassium hydrogenphosphate-citric acid TS.

Bromocresol purple-dipotassium hydrogenphosphate-citric acid TS Mix 30 mL of bromocresol purple-sodium hydroxide TS and 30 mL of dibasic potassium phosphate-citric acid buffer solution, pH 5.3, and wash with three 60-mL portions of chloroform.

Bromocresol purple-sodium hydroxide TS Triturate 0.4 g of bromocresol purple with 6.3 mL of dilute sodium hydroxide TS in a mortar, add water to make 250 mL, and filter if necessary.

Bromocresol purple TS Dissolve 0.05 g of bromocresol purple in 100 mL of ethanol (95), and filter if necessary.

Bromophenol blue $C_{19}H_{10}Br_4O_5S$ [K 8844, Special class]

Bromophenol blue-potassium biphthalate TS Dissolve 0.1 g of bromophenol blue in potassium biphthalate buffer solution, pH 4.6, to make 100 mL.

Bromophenol blue TS Dissolve 0.1 g of bromophenol blue in 100 mL of dilute ethanol, and filter if necessary.

0.05% Bromophenol blue TS Dissolve 0.01 g of bromophenol blue in water to make 20 mL.

Bromophenol blue TS, dilute Dissolve 0.05 g of bromophenol blue in 100 mL of ethanol (99.5). Prepare before use.

Bromophenol blue TS, pH 7.0 Mix 10 mL of bromophenol blue TS and 10 mL of ethanol (95), and adjust the pH to 7.0 with dilute sodium hydroxide TS.

***N*-Bromosuccinimide** $C_4H_4BrNO_2$ [K 9553, Special class]

***N*-Bromosuccinimide TS** Dissolve 1 g of *N*-bromosuccinimide in 1000 mL of water.

Bromothymol blue $C_{27}H_{28}Br_2O_5S$ [K 8842, Special class]

Bromothymol blue-sodium hydroxide TS To 0.2 g of powdered bromothymol blue add 5 mL of dilute sodium hydroxide TS and a small quantity of water, dissolve by shaking in a water bath at 50°C, then add water to make 100 mL.

Bromothymol blue TS Dissolve 0.1 g of bromothymol blue in 100 mL of dilute ethanol, and filter if necessary.

Bromovalerylurea $C_6H_{11}BrN_2O_2$ [Same as the namesake monograph]

Brucine See brucine dihydrate.

Brucine dihydrate $C_{23}H_{26}N_2O_4.2H_2O$ [K 8832, Brucine *n*-hydrate, Special class]

B-type erythrocyte suspension Prepare a suspension containing 1 vol% of erythrocyte separated from human B-type blood in isotonic sodium chloride solution.

Bufalin for component determination $C_{24}H_{34}O_4.xH_2O$ White, odorless, crystalline powder.

Absorbance $E^{1\%}_{1\,cm}$: 143 – 153 (0.01 g, methanol, 250 mL). Use the sample dried in a desiccator (silica gel) for 24 hours for the test.

Purity Related substances—Dissolve 0.040 g of bufalin for component determination in 5 mL of chloroform and use this solution as the sample solution. Pipet 1 mL of the sample solution, add chloroform to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of cyclohexane, acetone and chloroform (4:3:3) to a distance of about 14 cm, and air-dry. Spray evenly sulfuric acid, and heat at 100°C for 2 to 3 minutes: any spot other than the principal spot obtained from the sample solution is not larger, not more intense than the spot from the standard solution.