Content: not less than 99.0%. Component determination—Weigh accurately about 0.01 g of bufalin for component determination, previously dried in a desiccator (silica gel) for 24 hours, dissolve in methanol to make exactly 10 mL, and use this solution as the sample solution. Perform the test with 20 μL of the sample solution as directed under the Liquid Chromatography according to the following conditions. Measure the peak area by the automatic integration method, and calculate the amount of bufalin by the area percentage method.

Operating conditions

Detector: An ultraviolet absorption photometer (wavelength: 300 nm).

Column: A steinless steel column 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).

Flow rate: Adjust the flow rate so that the retention time of bufalin is about 6 minutes.

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. Proceed with 20 μL of this solution according to the above conditions. Use a column giving elution of bufalin, cinobufagin and resibufogenin in this order and completely resolving these peaks.

Detection sensitivity: Pipet 1 mL of the sample solution, add methanol to make exactly 100 mL, and use this solution as the standard solution (1). Pipet 1 mL of this solution, 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 bufalin obtained from 20 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of bufalin from 20 μL of the standard solution (1) is about 20% of the full scale.

Time span of measutrement: About twice as long as the retention time of bufalin after the solvent peak.

Bufexamac for assay $C_{12}H_{17}NO_3$ [Same as the monograph Bufexamac. When dried, it contains not less than 99.0% of $C_{12}H_{17}NO_3$. Proceed as directed in the Identification under Bufexamac Ointment: any peak other than the principal peak does not appear.]

***n*-Butanol** See 1-butanol.

***sec*-Butanol** See 2-butanol.

***t*-Butanol** $(CH_3)_3COH$ [K 8813, Special class]

***tert*-Butanol** See *t*-butanol.

1-Butanol $CH_3(CH_2)_2CH_2OH$ [K 8810, Special class]

2-Butanol $CH_3CH_2CH(OH)CH_3$ [K 8812, Special class]

2-Butanone $CH_3COC_2H_5$ [K 8900, Special class]

***N*-*t*-Butoxycarbonyl-L-glutamic acid-α-phenyl ester** $C_{16}H_{21}NO_6$ White powder.

Melting point: 95–104°C

Purity Related substances—Dissolve 0.01 g of *N*-*t*-butoxycarnonyl-L-glutamic acid-α-phenyl ester in 5 mL of dilute ethanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add dilute ethanol 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 10 μL each of the sample solution and the standard solution on three plates of silica gel with fluorescent indicator for thin-layer chromatography. Develop the first plate with a mixture of chloroform, ethyl acetate and acetic acid (100) (25:25:1), the second plate with a mixture of benzene, 1,4-dioxane and acetic acid (100) (95:25:4), and the third plate with a mixture of chloroform, methanol and acetic acid (100) (45:4:1) to a distance of about 12 cm, and air-dry these plates. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot obtained from the sample solution are not more intense than the spot from the standard solution in all plates.

***n*-Butyl acetate** $CH_3COOCH_2CH_2CH_2CH_3$ [K 8377, Special class]

***n*-Butylamine** $CH_3CH_2CH_2CH_2NH_2$ A colorless liquid, having an amine-like, characteristic odor. Miscible with water, with ethanol (95) and with diethyl ether. The solution in water shows alkalinity and rapidly absorbs carbon dioxide from the air.

Specific gravity d_{20}^{20}: 0.740 – 0.747

Distilling range: 76.5 – 79°C, not less than 96 vol%.

***n*-Butyl chloride** $CH_3(CH_2)_3Cl$ Clear and colorless liquid, miscible with ethanol (95) and with diethyl ether, practically insoluble in water. Boiling point: about 78°C

Refractive index n_D^{20}: 1.401 – 1.045

Specific gravity d_{20}^{20}: 0.884 – 0.890

***n*-Butyl formate** $HCOO(CH_2)_3CH_3$ Clear and colorless liquid, having a characteristic odor.

Specific gravity d_{20}^{20}: 0.884 – 0.904

***tert*-Butyl methyl ether** $(CH_3)_3COCH_3$ Clear colorless liquid, having a specific odor.

Specific gravity d_4^{20}: 0.7404

Refractive index n_D^{20}: 1.3689

Butyl parahydroxybenzoate $HOC_6H_4COOCH_2CH_2CH_2CH_3$ [Same as the namesake monograph in Part II]

Butyrolactone $C_4H_6O_2$ Clear, colorless to practically colorless liquid.

Specific gravity d_4^{25}: 1.128 – 1.135

Boiling point: 198 – 208°C

Cadmium acetate See cadmium acetate dihydrate.

Cadmium acetate dihydrate $Cd(CH_3COO)_2.2H_2O$ [K 8362, Special class]

Cadmium ground metal Cd [H 2113, First class]

Cadmium-ninhydrin TS Dissolve 0.05 g of cadmium acetate dihydrate in 5 mL of water and 1 mL of acetic acid (100), add 2-butanone to make 50 mL, and dissolve 0.1 g of ninhydrin in this solution. Prepare before use.

Caffeine $C_8H_{10}N_4O_2.H_2O$ [Same as the namesake monograph]

Caffeine, anhydrous $C_8H_{10}N_4O_2$ [Same as the namesake monograph]

Calcium carbonate $CaCO_3$ [K 8617, Special class]

Calcium chloride See calcium chloride dihydrate.

Calcium chloride dihydrate $CaCl_2.2H_2O$ [K 8122, Special class]

Calcium chloride for drying $CaCl_2$ [K 8124, For drying]

Calcium chloride for Karl Fischer method $CaCl_2$ [K 8125, For water determination]

Calcium chloride TS Dissolve 7.5 g of calcium chloride dihydrate in water to make 100 mm (0.5 mol/L).

Calcium hydroxide $Ca(OH)_2$ [K 8575, Special class]

Calcium hydroxide for pH determination [K 8575, Special class] Use the saturated solution, obtained in water between 23°C and 27°C, which has a pH of 12.45 at 25°C.

Calcium hydroxide pH standard solution See the pH Determination under the General Tests, Processes and Apparatus.

Calcium hydroxide TS To 3 g of calcium hydroxide add 1000 mL of cold distilled water, and occasionally shake the mixture vigorously for 1 hour. Allow to stand, and use the supernatant liquid (0.04 mol/L).

Calcium nitrate See calcium nitrate tetrahydrate.

Calcium nitrate tetrahydrate $Ca(NO_3)_2.4H_2O$ [K 8549, Special class]

Calcium oxide CaO [K 8410, Special class]

Camphor $C_{10}H_{16}O$ [Same as the monograph *d*-Camphor or *dl*-Camphor]

***d*-Camphorsulfonic acid** $C_{10}H_{16}O_4S$ White crystals or crystalline powder, having a characteristic odor. Very soluble in water, and soluble in chloroform.

Purity Clarity and color of solution—Dissolve 1.0 g of *d*-camphorsulfonic acid in 10 mL of water: the solution is clear and colorless or pale yellow.

Loss on drying: not more than 2.0% (1 g, 105°C, 5 hours).

Content: not less than 99.0%, calculated on the dried basis. Assay—Weigh accurately about 4 g of *d*-camphorsulfonic acid, dissolve in 50 mL of water, and titrate with 1 mol/L sodium hydroxide VS (indicator: 3 drops of methyl red TS). Perform a blank determination in the same manner.

Each mL of 1 mol/L sodium hydroxide VS
= 232.30 mg of $C_{10}H_{16}O_4S$

Capsaicin for component determination Use capsaicin for thin-layer chromatography meeting the following additional specifications.

Absorbance $E^{1\%}_{1cm}$ (281 nm): 97 - 105 (0.01 g, methanol, 200 mL). Use the sample dried in a desiccator (in vacuum, phosphorus (v) oxide, 40°C) for 5 hours for the test.

Purity Related substances—Dissolve 0.010 g of capsaicin for component determination in 50 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 20 μL each of the sample solution and the standard solution 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 area of the peaks other than capsaicin from the sample solution is not larger than the peak area of capsaicin from the standard solution.

Operating conditions

Detector, column, column temperature, mobile phase, and flow rate: Proceed the operating conditions in the Component determination under Capsicum.

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

System suitability

System performance, and system repeatability: Proceed the system suitability in the Component determination under Capsicum.

Test for required detectability: Pipet 1 mL of the standard solution, and add methanol to make exactly 20 mL. Confirm that the peak area of capsaicin from 20 μL of this solution is equivalent to 3.5 to 6.5% of that of capsaicin from the standard solution.

Capsaicin for thin-layer chromatography $C_{18}H_{27}NO_3$ White crystals, having a strong irritative odor. Very soluble in methanol, freely soluble in ethanol (95) and in diethyl ether, and practically insoluble in water.

Melting point: 64.5 - 66.5°C

Purity Related substances—Dissolve 0.020 g of capsaicin for thin-layer chromatography in 2 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 under Capsicum: any spot other than the principal spot at the *R*f value of about 0.5 from the sample solution is not more intense than the spot from the standard solution.

Carbazochrome $C_{10}H_{12}N_4O_3$ Yellow-red to red crystals or crystalline powder.

Melting point: about 222°C (with decomposition).

Content: not less than 98.0%. Assay—Dissolve about 0.2 g of carbazochrome, previously weighed accurately, in 20 mL of acetic acid (100) by heating, add 80 mL of acetic anhydride, cool, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 23.623 mg of $C_{10}H_{12}N_4O_3$

Carbazochrome sodium sulfonate for component determination [Same as the monograph Carbazochrome Sodium Sulfonate. It contains not less than 14.0% and not more than 15.0% of water, and not less than 99.0% of carbazochrome sodium sulfonate ($C_{10}H_{11}N_4NaO_5S$), calculated on the dehydrated basis.]

Carbon dioxide CO_2 [Same as the namesake monograph]

Carbon disulfide CS_2 [K 8732, Special class] Preserve

in tightly stoppered containers in a dark, cold place, remote from fire.

Carbon monoxide CO A toxic, colorless gas. Prepare by passing the gas generated by reacting formic acid with sulfuric acid through a layer of sodium hydroxide TS. Carbon monoxide from a metal cylinder may be used.

Carbon tetrachloride CCl_4 [K 8459, Special class]

Casein, milk [K 8234, Special class]

Casein peptone See peptone, casein.

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

Catechol $C_6H_4(OH)_2$ [K 8240, Special class]

Cefadroxil $C_{16}H_{17}N_3O_5S.H_2O$ [Same as the namesake monograph]

Cefdinir lactam ring-cleavage lactones $C_{14}H_{15}N_5O_6S_2$ A white to yellow powder. A mixture of 4 diastereoisomers.
Identification—Determine the infrared absorption spectrum of cefdinir lactam ring-cleavage lactones as directed in the paste method under the Infrared Spectrophotometry: it exhibits absorption at the wave numbers of about 1743 cm^{-1}, 1330 cm^{-1}, 1163 cm^{-1} and 1047 cm^{-1}.
Content: not less than 90%. Assay—Dissolve about 5 mg of cefdinir lactam ring-cleavage lactones in 5 mL of 0.1 mol/L phosphate buffer solution, pH 7.0, and use this solution as the sample solution. Perform the test with 5 μL of the sample solution as directed in the operating conditions of Purity (2) Related substances under Cefdinir, and calculate the areas of each peak by the automatic integration method. Determine the percent of the total peak area of 4 cefdinir lactam ring-cleavage lactones to the total area of all peaks.

Cefoselis-3-ene-isomer $C_{19}H_{22}N_8O_6S_2$ A white to yellowish white powder.
Identification—After drying under reduced pressure at 60°C for 3 hours, determine the infrared absorption spectrum of cefoselis-3-ene-isomer according to the paste method under the Infrared Spectrophotometry: it exhibits absorption at the wave numbers of about 3299 cm^{-1}, 1768 cm^{-1}, 1618 cm^{-1}, 1520 cm^{-1} and 865 cm^{-1}.
Content: not less than 90%. Assay—Dissolve about 2.5 mg of cefoselis-3-ene-isomer in 5 mL of 0.1 mol/L phosphate buffer solution, pH 7.0 and use this solution as the sample solution. Perform the test with 5 μL of the sample solution as directed in the Assay under Cefoselis Sulfate, and calculate the percentage of the peak area of cefoselis-3-ene-isomer to the total peak area by the automatic integration method.

Cellulose for thin-layer chromatography Use a high-grade cellulose prepared for thin-layer chromatography.

Cellulose with fluorescent indicator for thin-layer chromatography Use cellulose for thin-layer chromatography containing a suitable fluorescent substance.

Cephaeline hydrobromate $C_{28}H_{38}N_2O_4.2HBr.xH_2O$ A white or light-yellow crystalline powder.
Purity—Dissolve 0.01 g of cephaeline hydrobromate 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 10 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 operating conditions in the Component determination under Ipecac: the total peak area of peaks other than cephaeline from the sample solution is not larger than the peak area of cephaeline from the standard solution.

Ceric ammonium sulfate See cerium (IV) tetraammonium.

Ceric ammonium sulfate-phosphoric acid TS See cerium (IV) tetraammonium-phosphoric acid TS.

Ceric ammonium sulfate TS See cerium (IV) tetraammonium TS.

Cerium (III) nitrate hexahydrate $Ce(NO_3)_3.6H_2O$ A colorless or light yellow, crystalline powder. It dissolves in water.
Purity (1) Chloride: not more than 0.036%.
(2) Sulfate: not more than 0.120%.
Content: not less than 98.0%. Assay—To about 1.5 g of cerous nitrate, accurately weighed, add 5 mL of sulfuric acid, and heat it until white fumes are evolved vigorously. After cooling, add 200 mL of water, 0.5 mL of 0.1 mol/L silver nitrate VS, dissolve 5 g of ammonium persulfate, dissolve, and boil it for 15 minutes. After cooling, add 2 drops of 1,10-phenanthroline TS, and titrate with 0.1 mol/L ferrous ammonium sulfate VS until the pale blue color of the solution changes to red.

Each mL of 0.1 mol/L ferrous ammonium sulfate VS
= 43.42 mg of $Ce(NO_3)_3.6H_2O$

Cerium (III) nitrate TS Dissolve 0.44 g of cerium (III) nitrate hexahydrate in water to make 1000 mL.

Cerium (IV) diammonium nitrate $Ce(NH_4)_2(NO_3)_6$ [K 8556, Special class]

Cerium (IV) diammonium nitrate TS Dissolve 6.25 g of cerium (IV) diammonium nitrate in 160 mL of diluted dilute nitric acid (9 in 50). Use within 3 days.

Cerium (IV) tetraammonium sulfate $Ce(SO_4)_2.2(NH_4)_2SO_4.4H_2O$ [K 8977, Special class]

Cerium (IV) tetraammonium sulfate-phosphoric acid TS Dissolve 0.1 g of cerium (IV) tetraammonium sulfate in diluted phosphoric acid (4 in 5) to make 100 mL.

Cerium (IV) tetraammonium sulfate TS Dissolve 6.8 g of cerium (IV) tetraammonium sulfate in diluted sulfuric acid (3 in 100) to make 100 mL.

Cerous nitrate See cerium (III) nitrate hexahydrate.

Cerous nitrate TS See cerium (III) nitrate TS.

Cetanol [Same as the namesake monograph in Part II]

Cetrimide $C_{17}H_{38}BrN$ White to pale yellowish white powder, having a faint, characteristic odor.
Purity Clarity of solution—Dissolve 1.0 g of cetrimide in 5 mL of water: the solution is clear.
Content: not less than 96.0%. Assay—Weigh accurately about 2 g of cetrimide, previously dried, and dissolve in water to make exactly 100 mL. Pipet 25 mL of this solution into a separator, add 25 mL of chloroform, 10 mL of 0.1 mol/L sodium hydroxide VS and 10 mL of a freshly pre-

pared solution of potassium iodide (1 in 20), shake well, allow to stand, and remove the chloroform layer. Wash the solution with three 10-mL portions of chloroform, take the water layer, and add 40 mL of hydrochloric acid. After cooling, titrate with 0.05 mol/L potassium iodide VS until the deep brown color of the solution almost disappears, add 2 mL of chloroform, and titrate again until the red-purple color of the chloroform layer disappears. The end point is reached when the red-purple color of the chloroform layer no more reappears within 5 minutes after the chloroform layer is decolorized. Perform a blank determination with 20 mL of water, 10 mL of a solution of potassium iodide (1 in 20) and 40 mL of hydrochloric acid.

Each mL of 0.05 mol/L potassium iodate VS
= 33.640 mg of $C_{17}H_{38}BrN$

Chenodeoxycholic acid for thin-layer chromatography $C_{24}H_{40}O_4$ White crystals or crystalline powder. Very soluble in methanol and in acetic acid (100), freely soluble in ethanol (95), soluble in acetone, sparingly soluble in ethyl acetate, slightly soluble in chloroform, and practically insoluble in water.

Melting point: about 119°C (recrystallize from ethyl acetate).

Purity Related substances—Dissolve 0.025 g of chenodeoxycholic acid for thin-layer chromatography in a mixture of chloroform and ethanol (95) (9:1) to make exactly 250 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 at the *R*f value of about 0.4 does not appear.

Content: not less than 98.0%. Assay—Weigh accurately about 0.5 g of chenodeoxycholic acid for thin-layer chromatography, previously dried under reduced pressure (phosphorus (V) oxide) at 80°C for 4 hours, and dissolve in 40 mL of neutralized ethanol and 20 mL of water. Add 2 drops of phenolphthalein TS, and titrate with 0.1 mol/L sodium hydroxide VS. Near the end point add 100 mL of freshly boiled and cooled water, and titrate again.

Each mL of 0.1 mol/L sodium hydroxide VS
= 39.258 mg of $C_{24}H_{40}O_4$

Chikusetsusaponin IV for thin-layer chromatography $C_{47}H_{74}O_{18}.nH_2O$ White crystalline powder. Freely soluble in methanol and in ethanol (95), and practically insoluble in diethyl ether.

Melting point: about 215°C (with decomposition).

Purity Related substances—Dissolve 2 mg of chikusetsusaponin IV for thin-layer chromatography in 1 mL of methanol, and perform the test with 5 μL of this solution as directed in the Identification under Panax Rhizome: any spot other than the principal spot at the *R*f value of about 0.4 does not appear.

Chloral hydrate $CCl_3CH(OH)_2$ [K 8869: 1961, First class]

Chloral hydrate TS Dissolve 5 g of chloral hydrate in 3 mL of water.

Chloramine See sodium toluensulfonchloramide trihydrate.

Chloramine TS See sodium toluensulfonchloramide TS.

Chloramphenicol $C_{11}H_{12}Cl_2N_2O_5$ [Same as the monograph Chloramphenicol]

Chlorauric acid See hydrogen tetrachloroaurate (III) tetrahydrate.

Chlorauric acid TS See hydrogen tetrachloroaurate (III) tetrahydrate TS.

Chlordiazepoxide $C_{16}H_{14}ClN_3O$ [Same as the namesake monograph]

Chlordiazepoxide for assay $C_{16}H_{14}ClN_3O$ [Same as the monograph Chlordiazepoxide. When dried, it contains not less than 99.0% of $C_{16}H_{14}ClN_3O$].

Chlorinated lime [Same as the namesake monograph in Part II]

Chlorinated lime TS Triturate 1 g of chlorinated lime with 9 mL of water, and filter. Prepare before use.

Chlorine Cl_2 A yellow-green gas, having a suffocating odor. It is heavier than air, and dissolves in water. Prepare from chlorinated lime with hydrochloric acid. Chlorine from a metal cylinder may be used.

Chlorine TS Use a saturated solution of chlorine in water. Preserve this solution in fully filled, light-resistant, glass-stopered bottles, preferably in a cold place.

Chloroacetic acid $C_2H_3ClO_2$ [K 8899, Special class]

***p*-Chloroaniline** See 4-chloroaniline

4-Chloroaniline $H_2NC_6H_4Cl$ White crystals or crystalline powder. Freely soluble in ethanol (95) and in acetone, and soluble in hot water.

Melting point: 70 - 72°C

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

***p*-Chlorobenzene sulfonamide** See 4-chlorobenzene sulfonamide.

4-Chlorobenzene sulfonamide $ClC_6H_4SO_2NH_2$ White to pale yellow, odorless, crystalline powder. Dissolves in acetone.

Purity Related substances—Dissolve 0.60 g of 4-chlorobenzene sulfonamide in acetone to make exactly 300 mL, and perform the test with 5 μL of this solution as directed in the Purity (5) under Chlorpropamide: any spot other than the principal spot at the *R*f value of about 0.5 does not appear.

***p*-Chlorobenzoic acid** See 4-chlorobenzoic acid.

4-Chlorobenzoic acid ClC_6H_4COOH White crystals or powder. Sparingly soluble in ethanol (95), slightly soluble in chloroform, and practically insoluble in water.

Melting point: 238 - 242°C

Content: not less than 99.0%. Assay—Weigh accurately about 0.3 g of 4-chlorobenzoic acid, dissolve in 30 mL of neutralized ethanol, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS).

Each mL of 0.1 mol/L sodium hydroxide VS
= 15.657 mg of $C_7H_5ClO_2$

Chloroform $CHCl_3$ [K 8322, Special class]

Chloroform, ethanol-free Mix 20 mL of chloroform with 20 mL of water, gently shake for 3 minutes, separate the chloroform layer, wash the layer again with two 20-mL portions of water, and filter it through dry filter paper. To