

Cupric sulfate See copper (II) sulfate pentahydrate.

Cupric sulfate, anhydrous See copper (II) sulfate (anhydrous).

Cupric sulfate-pyridine TS See copper (II) sulfate-pyridine TS.

Cupric sulfate solution, alkaline See copper (II) sulfate solution, alkaline.

Cupric sulfate TS See copper (II) sulfate TS.

1 mol/L Cupriethylenediamine TS Put 100 g of copper (II) hydroxide in a 1-L thick-walled bottle marked a 500-mL line, and add water to make 500 mL. Connect the bottle with a liquid introducing funnel, a nitrogen introducing glass tube and a gas removing glass tube. Adjust so that the lower end of the nitrogen introducing tube is located at about 1.3 cm above of the bottom of the bottle. Introduce the nitrogen for about 3 hours to replacing the inside gas by adjusting the pressure (about 14 kPa) to get a mild bubbling. Then add gradually 160 mL of ethylenediamine TS through the funnel while introducing the nitrogen and cooling the bottle with the running water, and replace the funnel with a glass rod to close tightly. After introducing the nitrogen for further 10 minutes, replace the gas removing tube with a glass rod to close tightly. Keep the inside pressure with the nitrogen to about 14 kPa. After allowing the bottle to stand for about 16 hours while occasional shaking, filter the content if necessary using a glass-filter under reducing pressure, and reserve under nitrogen atmosphere. The concentration of copper (II) ion of this solution is about 1.3 mol/L. Determine the concentration of ethylenediamine of this solution X (mol/L) and copper (II) ion Y (mol/L) by the following Assays, and adjust to that X is 1.96–2.04, Y is 0.98–1.02 and X/Y is 1.96–2.04 by adding water, copper (II) hydroxide or ethylenediamine TS, then determine X and Y again in the same manner, and use this solution as the test solution.

Assay (1) Ethylenediamine—Pipet 1 mL (V_1) of the solution to be assayed, add 60 mL of water, and titrate with 0.1 mol/L hydrochloric acid VS (pH Determination method; End point is about pH 8.4).

$$X = \frac{N_1 a}{V_1}$$

X: Concentration of ethylenediamine (mol/L)

a: Volume of 0.1 mol/L hydrochloric acid VS consumed for the titration (mL)

N_1 : Concentration of 0.1 mol/L hydrochloric acid VS (mol/L)

(2) **Copper (II) ion**—Pipet 2 mL (V_2) of the solution to be assayed, add 20 mL of water, about 3 g of potassium iodide and 50 mL of 2 mol/L sulfuric acid TS, shake for 5 minutes, and titrate the liberated iodine with 0.1 mol/L sodium thiosulfate VS. When the solution turns light yellow at near the end point add 3 mL of starch TS and 10 mL of a solution of ammonium thiocyanate (2 in 10), and then titrate until the blue color disappears.

$$Y = \frac{N_2 b}{V_2}$$

Y: Concentration of copper (II) ion (mol/L)

b: Volume of 0.1 mol/L sodium thiosulfate VS consumed for the titration (mL)

N_2 : Concentration of 0.1 mol/L sodium thiosulfate VS (mol/L)

Curcumin $C_{21}H_{20}O_6$ [K 8297, Special class]

Curcumin TS Dissolve 0.125 g of curcumin in acetic acid (100) to make 100 mL. Prepare before use.

Cyanoacetic acid $C_3H_3NO_2$ White to light yellow crystals. Very soluble in water.

Content: not less than 99%. **Assay**—Weigh accurately about 300 mg of cyanoacetic acid, add 25 mL of water and 25 mL of ethanol (95) to dissolve, and titrate with 0.1 mol/L sodium hydroxide VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

$$\begin{aligned} \text{Each mL of 0.1 mol/L sodium hydroxide VS} \\ = 85.06 \text{ mg of } C_3H_3NO_2 \end{aligned}$$

Cyanocobalamin $C_{63}H_{88}CoN_{14}O_{14}P$ [Same as the namesake monograph]

Cyanogen bromide TS To 100 mL of ice-cold water add 1 mL of bromine, shake vigorously, and add ice-cold potassium cyanide TS dropwise until the color of bromine just disappears. Prepare this test solution in a hood before use.

On handling this solution, be careful not to inhale its vapors, which are very toxic.

7% Cyanopropyl-7% phenylmethylsilicone polymer for gas chromatography Prepared for gas chromatography.

Cyanopropylsilanized silica gel for liquid chromatography Prepared for liquid chromatography.

Cyclohexane C_6H_{12} [K 8464, Special class]

Cyclohexylamine for thin-layer chromatography

$C_6H_{11}NH_2$ A colorless and clear liquid, having a characteristic amine-like odor. Miscible with water, *N,N*-dimethylformamide and acetone.

Purity Related substances—Dissolve 0.04 g of cyclohexylamine for thin-layer chromatography in a mixture of *N,N*-dimethylformamide and acetone (1:1) to make exactly 50 mL. Proceed with this solution as directed in the Purity (5) Related substances, cyclohexylamine, under Acetohexamide: any spot other than the principal spot at the *R_f* value of about 0.4 does not appear.

L-Cysteine hydrochloride See L-cysteine hydrochloride monohydrate.

L-Cysteine hydrochloride monohydrate

$HSCH_2CH(NH_2)COOH \cdot HCl \cdot H_2O$ [K 8470, Special class]

L-Cystine $HOOCCH(NH_2)CH_2SSCH_2CH(NH_2)COOH$ [K 9048, L(-)-Cystine, Special class]

Cytosine $C_4H_5N_3O$ White, crystalline powder or powder.

Absorbance $E_{1cm}^{1\%}$ (276 nm): not less than 800 (after drying, 0.04 g, 10,000 mL of 0.1 mol/L hydrochloric acid TS).

Dacuronium Bromide for thin-layer chromatography

$C_{33}H_{58}Br_2N_2O_3$ White crystalline powder. Very soluble in water, freely soluble in ethanol (95), and practically insoluble in acetic anhydride and in diethyl ether. Hygroscopic.

Identification—Determine the infrared absorption spectrum of dacuronium bromide for thin-layer chromatography according to the potassium bromide disk

method under the Infrared Spectrophotometry: it exhibits the absorptions at the wave numbers at about 2938 cm^{-1} , 1737 cm^{-1} , 1630 cm^{-1} , 1373 cm^{-1} , 1233 cm^{-1} and 1031 cm^{-1} .

Purity Related substances—Dissolve 0.010 g of dacturionium bromide for thin-layer chromatography in 2 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of this 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 in the Purity (2) Related substances under Pancuronium Bromide: the spots other than the principal spot from the sample solution do not show more intense color than the spot from the standard solution.

Water: not more than 1.0% (1 g, volumetric titration, direct titration).

Content: not less than 98.0%, calculated on the dehydrated basis. **Assay**—Weigh accurately about 0.2 g of dacturionium bromide for thin-layer chromatography, dissolve in 50 mL of acetic anhydride by warming, 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
= 34.532 mg of $\text{C}_{33}\text{H}_{58}\text{Br}_2\text{N}_2\text{O}_3$

***p,p'*-DDD** (2,2-Bis(4-chlorophenyl)-1,1-dichloroethane) $\text{C}_{14}\text{H}_{10}\text{Cl}_4$

Melting point: 108 – 110°C

Purity Related substances—Dissolve 0.010 g of *p,p'*-DDD in 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 2 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 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 area other than *p,p'*-DDD from the sample solution is not larger than the peak area of *p,p'*-DDD 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 exactly 20 mL, and use this solution as the standard solution (2). Adjust the detection sensitivity so that the peak area of *p,p'*-DDD obtained from 1 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of *p,p'*-DDD 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 *p,p'*-DDD after the solvent peak.

***p,p'*-DDE** (2,2-Bis(4-chlorophenyl)-1,1-dichloroethylene) $\text{C}_{14}\text{H}_8\text{Cl}_4$

Melting point: 88 – 90°C

Purity Related substances—Proceed as directed in the Purity of *p,p'*-DDD using the following standard solution

(1).

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

***o,p'*-DDT** (1,1,1-Trichloro-2-(2-chlorophenyl)-2-(4-chlorophenyl)ethane) $\text{C}_{14}\text{H}_9\text{Cl}_5$

Melting point: 73 – 75°C

Purity Related substances—Proceed as directed in the Purity of *p,p'*-DDD.

***p,p'*-DDT** (1,1,1-Trichloro-2,2-bis(4-chlorophenyl)ethane) $\text{C}_{14}\text{H}_9\text{Cl}_5$

Melting point: 108 – 110°C

Purity Related substances—Proceed as directed in the Purity of *p,p'*-DDD using the following standard solution (1).

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

DEAE-Cross-linking dextran anion exchanger (Cl type), slightly alkaline Slightly alkaline anion exchanger prepared by introducing diethylaminoethyl group into cross-linking dextran of gel filtration carrier.

Decolorized fuchsin TS Add 1 g of fuchsin in 100 mL of water, heat at about 50°C, then cool with occasional shaking. After standing for 48 hours, mix and filter. To 4 mL of the filtration add 6 mL of hydrochloric acid and water to make 100 mL. Use after standing for at least 1 hour. Prepare before use.

***n*-Decyl trimethylammonium bromide** $\text{C}_{13}\text{H}_{30}\text{NBr}$
White powder.

Melting point: about 232°C (with decomposition).

Content: not less than 99%. **Assay**—Weigh accurately about 0.5 g of *n*-decyl trimethylammonium bromide, dissolve in 50 mL of water, and titrate with 0.1 mol/L silver nitrate VS (indicator: 1 mL of potassium chromate TS). Perform a blank determination in the same manner and make any necessary correction.

Each mL of 0.1 mol/L silver nitrate VS
= 28.029 mg of $\text{C}_{13}\text{H}_{30}\text{NBr}$

0.005 mol/L *n*-Decyl trimethylammonium bromide TS Dissolve 6.94 g of potassium dihydrogenphosphate, 3.22 g of disodium hydrogenphosphate 12-water and 1.40 g of *n*-decyl trimethylammonium bromide in water to make 1000 mL.

Defibrinated blood of rabbit Transfer 100 mL of blood obtained from rabbit to a flask, put in about 20 glass balls 8 mm in diameter, shake for 5 minutes gently, and filter through gauze. Prepare before use.

Dehydrated ethanol See ethanol (99.5).

Dehydrated ether See diethyl ether.

Dehydrated pyridine See pyridine, dehydrated.

Dehydrocorydaline nitrate for component determination $\text{C}_{22}\text{H}_{24}\text{N}_2\text{O}_7$ Yellow, crystals or crystalline powder. It is sparingly soluble in methanol, slightly soluble in water, in ethanol (95) and in acetonitrile, and practically insoluble in diethyl ether.

Melting point: about 240°C (with decomposition).

Absorbance $E_{1\text{cm}}^{1\%}$ (333 nm): 577 – 642 [3 mg after drying in a desiccator (silica gel) for not less than 1 hour, water, 500 mL].

Purity Related substances—(1) Dissolve 5.0 mg of dehydrocorydaline nitrate for component determination in 1 mL of a mixture of water and methanol (1:1), and use this solution as the sample solution. Pipet 0.5 mL of the sample solution, add a mixture of water and methanol (1:1) 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 5 μL of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop immediately with a mixture of methanol, water and acetic acid (100) (20:1:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm) and then spray Dragendorff's TS on the plate: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution in either case.

(2) Dissolve 5.0 mg of dehydrocorydaline nitrate 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. Perform the test with 5 μL 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 in each solution: the total area of peaks other than dehydrocorydaline and the solvent from the sample solution is not larger than the peak area of dehydrocorydaline from the standard solution.

Operating conditions

Column, column temperature, mobile phase, and flow rate: Proceed the operating conditions in the Component determination under Corydalis Tuber.

Detector: Ultraviolet absorption photometer (wavelength: 230 nm)

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

System performance and system repeatability: Proceed the system suitability in the Component determination under Corydalis Tuber.

Test for required detectability: To exactly 1 mL of the standard solution add the mobile phase to make exactly 20 mL. Confirm that the peak area of dehydrocorydaline obtained from 5 μL of this solution can be measured by the automatic integration method, and that the peak height of dehydrocorydaline obtained from 5 μL of the standard solution is equivalent to around 20% of the full scale.

***N*-Demethylroxithromycin** $\text{C}_{40}\text{H}_{74}\text{N}_2\text{O}_{15}$ White powder.

Identification—Determine the infrared absorption spectrum of *N*-demethylroxithromycin in a solution in chloroform (1 in 1000) according to the solution method under the Infrared Spectrophotometry using a 0.1-mm cell made of potassium bromide: it exhibits absorption at the wave numbers of about 3600 cm^{-1} , 3524 cm^{-1} , 3445 cm^{-1} , 3335 cm^{-1} , 1730 cm^{-1} and 1627 cm^{-1} .

2'-Deoxyuridine for liquid chromatography $\text{C}_9\text{H}_{12}\text{N}_2\text{O}_5$ White, crystalline powder.

Melting point: 162 – 166°C

Purity—Dissolve 3 mg of 2'-deoxyuridine for liquid chromatography in diluted methanol (1 in 25) to make 50 mL. Perform the test with 10 μL of this solution as directed under the Liquid Chromatography according to the operating conditions in the Purity under Idoxuridine Ophthalmic Solution. Measure each peak area by the automatic integration method to the range about twice the retention time of 2'-deoxyuridine, and calculate the amount of 2'-deoxyuridine by the area percentage method: it shows a purity of not less than 98.5%.

Content: not less than 98.5%. **Assay**—Weigh accurately about 5 mg of 2'-deoxyuridine for liquid chromatography, previously dried in vacuum at 60°C for 3 hours, and dissolve in water to make exactly 250 mL. Pipet 10 mL of this solution, dilute with water to make exactly 20 mL. Perform the test with this solution as directed under the Ultraviolet-visible Spectrophotometry, and determine absorbance *A* at the maximum wavelength at about 262 nm.

$$\begin{aligned} &\text{Amount (mg) of deoxyuridine (C}_9\text{H}_{12}\text{N}_2\text{O}_5) \\ &= \frac{A}{447} \times 5000 \end{aligned}$$

Deuterated dimethylsulfoxide for nuclear magnetic resonance spectroscopy $(\text{CD}_3)_2\text{SO}$ Prepared for nuclear magnetic resonance spectroscopy.

Deuterated hydrochloric acid for nuclear magnetic resonance spectroscopy DCl Prepared for nuclear magnetic resonance spectroscopy.

Deuterated methanol for nuclear magnetic resonance spectroscopy CD_3OD Prepared for nuclear magnetic resonance spectroscopy.

Deuteriochloroform for nuclear magnetic resonance spectroscopy CDCl_3 Prepared for nuclear magnetic resonance spectroscopy.

Devarda's alloy [K 8653, Special class]

Diacetyl $\text{CH}_3\text{COCOCH}_3$ A yellow to yellow-green, clear liquid, having a strong, pungent odor. Miscible with ethanol (95) and with diethyl ether, and freely soluble in water.

Congealing point: –2.0 – –5.5°C

Refractive index n_D^{20} : 1.390 – 1.398

Specific gravity d_{20}^{20} : 0.98 – 1.00

Boiling point: 85 – 91°C

Purity Clarity of solution—Dissolve 1.0 g of diacetyl in 10 mL of water: the solution is clear.

Content: not less than 95.0%. **Assay**—Weigh accurately about 0.4 g of diacetyl, add exactly 75 mL of hydroxylamine TS, and heat on a water bath for 1 hour under a reflux condenser. After cooling, titrate the excess hydroxylamine with 0.5 mol/L hydrochloric acid VS until the color of the solution changes from blue to yellow-green through green (indicator: 3 drops of bromophenol blue TS). Perform a blank determination in the same manner.

$$\begin{aligned} &\text{Each mL of 0.5 mol/L hydrochloric acid VS} \\ &= 21.523\text{ mg of C}_4\text{H}_6\text{O}_2 \end{aligned}$$

Diacetyl TS Dissolve 1 mL of diacetyl in water to make 100 mL, and dilute 5 mL of this solution with water to make 100 mL. Prepare before use.

2,3-Diaminonaphthalene $C_{10}H_{10}N_2$ Light yellow-brown crystals or powder. Slightly soluble in ethanol (95) and in diethyl ether, and practically insoluble in water.

Melting point: 193 – 198°C

Sensitivity—Pipet separately 40 mL each of the selenium standard solution and diluted nitric acid (1 in 60) as the blank solution into beakers, and to these solutions add ammonia solution (28) to adjust the pH to between 1.8 and 2.2. Dissolve 0.2 g of hydroxylammonium chloride in each of these solutions under gentle shaking, add 5 mL of 2,3-diaminonaphthalene TS, mix by shaking, and allow to stand for 100 minutes. Transfer these solutions to separators separately, rinse the beakers with 10 mL of water, add these rinsings to the separators, extract each with 5.0 mL of cyclohexane by thorough shaking for 2 minutes, and centrifuge the cyclohexane layers to remove moisture. When the absorbance at 378 nm of cyclohexane extract obtained from selenium standard solution is determined using the solution obtained from the blank solution as the reference solution as directed under the Ultraviolet-visible Spectrophotometry, it is not less than 0.08.

Selenium standard solution—Weigh accurately 0.040 g of selenium, dissolve in 100 mL of diluted nitric acid (1 in 2), by heating on water bath if necessary, and add water to make exactly 1000 mL. Pipet 5 mL of this solution, and add water to make exactly 200 mL. Pipet 2 mL of this solution, and add diluted nitric acid (1 in 60) to make exactly 50 mL. Prepare before use. This solution contains 0.04 µg of selenium (Se) per mL.

2,3-Diaminonaphthalene TS Dissolve 0.10 g of 2,3-diaminonaphthalene and 0.5 g of hydroxylammonium chloride in 0.1 mol/L hydrochloric acid TS to make 100 mL.

2,4-Diaminophenol hydrochloride $C_6H_8N_2O \cdot 2HCl$ Pale yellow-brown to grayish yellow-green crystalline powder. Freely soluble in water, slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

Purity Clarity of solution—Dissolve 1.0 g of 2,4-diaminophenol hydrochloride in 20 mL of water: the solution is clear or a slight turbidity is produced.

Loss on drying: not more than 0.5% (1 g, 105°C, 3 hours).

Residue on ignition: not more than 0.5% (1 g).

Content: not less than 98.0%. *Assay*—Weigh accurately about 0.2 g of 2,4-diaminophenol hydrochloride, dissolve in 50 mL of water, and titrate with 0.1 mol/L silver nitrate VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L silver nitrate VS
= 9.854 mg of $C_6H_8N_2O \cdot 2HCl$

2,4-Diaminophenol hydrochloride TS Dissolve 1 g of 2,4-diaminophenol hydrochloride and 20 g of sodium bisulfite in 100 mL of water, and filter, if necessary.

Diammonium hydrogen citrate $C_6H_{14}N_2O_7$ [K 8284, Special class]

Diammonium hydrogenphosphate $(NH_4)_2HPO_4$ [K 9016, Special class]

Diazobenzenesulfonic acid TS Weigh 0.9 g of sulfanilic acid, previously dried at 105°C for 3 hours, dissolve it in 10 mL of dilute hydrochloric acid by heating, and add water to make 100 mL. Pipet 3.0 mL of this solution, add 2.5 mL of sodium nitrite TS, and allow to stand for 5 minutes while

cooling with ice. Then add 5 mL of sodium nitrite TS and water to make 100 mL, and allow to stand in ice water for 15 minutes. Prepare before use.

Diazobenzenesulfonic acid TS, concentrated Weigh 0.2 g of sulfanilic acid, previously dried at 105°C for 3 hours, dissolve it in 20 mL of 1 mol/L hydrochloric acid TS by warming. Cool this solution with ice, and add 2.2 mL of a solution of sodium nitrite (1 in 25) dropwise under stirring. Allow to stand in ice water for 10 minutes, and add 1 mL of a solution of sulfaminic acid (1 in 20). Prepare before use.

Diazo TS Weigh accurately 0.9 g of sulfanilic acid, add 0.9 mL of hydrochloric acid and 20 mL of water, and dissolve by heating. After cooling, filter, and dilute the filtrate with water to make exactly 100 mL. Pipet 1.5 mL of this solution, cool in an ice bath, and add exactly 1 mL of sodium nitrite solution (1 in 20) dropwise, while shaking. Cool in an ice bath for 10 minutes, add cold water to make exactly 50 mL. Store in a cold place, and use within 8 hours.

Dibasic ammonium phosphate See diammonium hydrogenphosphate.

Dibasic potassium phosphate See dipotassium hydrogenphosphate.

Dibasic potassium phosphate-citric acid buffer solution, pH 5.3 See dipotassium hydrogenphosphate-citric acid buffer solution, pH 5.3.

1 mol/L Dibasic potassium phosphate TS for buffer solution See 1 mol/L dipotassium hydrogenphosphate TS for buffer solution.

Dibasic sodium ammonium phosphate See ammonium sodium hydrogenphosphate tetrahydrate.

Dibasic sodium phosphate See disodium hydrogenphosphate 12-water.

Dibasic sodium phosphate TS See disodium hydrogenphosphate TS.

Dibasic sodium phosphate, anhydrous See disodium hydrogenphosphate.

Dibasic sodium phosphate, anhydrous, for pH determination See disodium hydrogenphosphate for pH determination.

Dibasic sodium phosphate-citric acid buffer solution, pH 4.5 See disodium hydrogenphosphate-citric acid buffer solution, pH 4.5.

Dibasic sodium phosphate-citric acid buffer solution, pH 5.4 See disodium hydrogenphosphate-citric acid buffer solution, pH 5.4.

Dibasic sodium phosphate-citric acid buffer solution, pH 6.0 See disodium hydrogenphosphate-citric acid buffer solution, pH 6.0.

0.05 mol/L Dibasic sodium phosphate TS See 0.05 mol/L disodium hydrogenphosphate TS.

0.5 mol/L Dibasic sodium phosphate TS See 0.5 mol/L disodium hydrogenphosphate TS.

Dibenzyl $C_{14}H_{14}$ White crystals, freely soluble in diethyl ether, soluble in methanol and in ethanol (95), and practically insoluble in water.