Each mL of 0.1 mol/L perchloric acid VS
= 32.832 mg of $C_{17}H_{16}N_2O_5$

Dimorpholamine for assay [Same as the monograph Dimorpholamine. When dried, it contains not less than 99.0% of dimorpholamine ($C_{20}H_{38}N_4O_4$).

***m*-Dinitrobenzen** See 1,3-dinitrobenzen.

1,3-Dinitrobenzene $C_6H_4(NO_2)_2$ [K 8482, *m*-Dinitrobenzene, Special class]

1,3-Dinitrobenzene TS Dissolve 1 g of 1,3-dinitrobenzene in 100 mL of ethanol (95). Prepare before use.

1,3-Dinitrobenzene TS, alkaline Mix 1 mL of tetramethylammonium hydroxide and 140 mL of ethanol (99.5), titrate a part of the mixture with 0.01 mol/L hydrochloric acid VS, and dilute the remainder with ethanol (99.5) to give a 0.008 mol/L solution. Before use, mix 40 mL of this solution with 60 mL of a solution of 1,3-dinitrobenzene in benzene (1 in 20).

***m*-Dinitrobenzene TS** See 1,3-dinitrobenzene TS.

2,4-Dinitrochlorobenzene See 1-chloro-2, 4-dinitrobenzene.

2,4-Dinitrofluorobenzene See 1-fluoro-2, 4-dinitrobenzene.

***m*-Dinitrobenzene TS, alkaline** See 1,3-dinitrobenzene TS, alkaline.

2,4-Dinitrophenol $C_6H_4N_2O_5$ [K 8467: 1972, Special class]

2,4-Dinitrophenol TS Dissolve 0.5 g of 2,4-dinitrophenol in 100 mL of ethanol (95).

2,4-Dinitrophenylhydrazine $(NO_2)_2C_6H_3NHNH_2$ [K 8480, Special class]

2,4-Dinitrophenylhydrazine-diethylene glycol dimethyl ether TS Dissolve 3 g of 2,4-dinitrophenylhydrazine in 100 mL of diethylene glycol dimethyl ether while heating, cool, and filter if necessary.

2,4-Dinitrophenylhydrazine-ethanol TS Dissolve 1.5 g of 2,4-dinitrophenylhydrazine in a cold mixture of 10 mL of sulfuric acid and 10 mL of water, then add a mixture of 1 volume of aldehyde-free ethanol and 3 volumes of water to make 100 mL, and filter if necessary.

2,4-Dinitrophenylhydrazine TS Dissolve 1.5 g of 2,4-dinitrophenylhydrazine in a cold mixture of 10 mL of sulfuric acid and 10 mL of water, then add water to make 100 mL, and filter if necessary.

Dinonyl phthalate $C_6H_4(COOC_9H_{19})_2$ Colorless to pale yellow, clear liquid.

Specific gravity d_{20}^{20}: 0.967 - 0.987

Acid value: not more than 2.

Dioxane See 1,4-dioxane.

1,4-Dioxane $C_4H_8O_2$ [K 8461, Special class]

Diphenhydramine $C_{17}H_{21}NO$ [Same as the namesake monograph]

Diphenhydramine tannate [Same as the namesake monograph]

Diphenyl $C_{12}H_{10}$ White crystals or crystalline powder, having a characteristic odor. Freely soluble in acetone and in diethyl ether, soluble in ethanol (95), and practically insoluble in water.

Melting point: 68 - 72°C

Purity—Dissolve 0.1 g of diphenyl in 5 mL of acetone and use this solution as the sample solution. Perform the test with 2 μL of this solution 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 diphenyl by the area percentage method: it shows the purity of not less than 98.0%.

Operating conditions

Detector: Hydrogen flame-ionization detector.

Column: A glass tube about 3 mm in inside diameter and about 2 m in length, packed with 150 to 180 μm mesh siliceous earth for gas chromatography coated with 10% of polyethylene glycol 20 M for thin-layer chromatography.

Column temperature: A constant temperature of about 180°C.

Carrier gas: Nitrogen

Flow rate: Adjust the flow rate so that the retention time of diphenyl is about 8 minutes.

Detection sensitivity: Adjust the detection sensitivity so that the peak height of diphenyl obtained from 2 μL of the slution prepared by adding acetone to 1.0 mL of the sample solution to make 100 mL, is 5 % to 15% of the full scale.

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

Diphenylamine $(C_6H_5)_2NH$ [K 8487, Special class]

Diphenylamine-acetic acid TS Dissolve 1.5 g of diphenylamine in 1.5 mL of sulfuric acid and acetic acid (100) to make 100 mL.

Diphenylamine-acetic acid (100) TS See diphenilamine-acetic acid TS.

Diphenylamine TS Dissolve 1 g of diphenylamine in 100 mL of sulfuric acid. Use the colorless solution.

Diphenylcarbazide See 1,5-diphenilcarbazide.

1,5-Diphenylcarbazide $C_{13}H_{14}N_4O$ [K 8488, Special class]

Diphenylcarbazide TS See 1,5-diphenilcarbazide TS.

1,5-Diphenylcarbazide TS Dissolve 0.2 g of 1,5-diphenylcarbazide in 100 mL of a mixture of ethanol (95) and acetic acid (100) (9:1).

Diphenylcarbazone [K 8489, Speical class]

Diphenylcarbazone TS Dissolve 1 g of diphenylcarbazone in ethanol (95) to make 1000 mL.

Diphenyl ether $C_{12}H_{10}O$ Colorless crystals, having a geranium-like aroma. Dissolves in alcohol (95) and in diethyl ether, and practically insoluble in water.

Specific gravity d_{20}^{20}: 1.072 - 1.075

Boiling point: 254 - 259°C

Melting point: 28°C

Diphenyl imidazole $C_{15}H_{12}N_2$ White crystals or crystalline powder, freely soluble in acetic acid (100), and sparingly soluble in methanol.

Melting point: 234 - 238°C

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

hours).

Content: not less than 99.0%. Assay—Dissolve about 0.3 g of diphenyl imidazole, previously dried and weighed accurately, in 70 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (indicator: 2 drops of crystal vioret TS).

Each mL of 0.1 mol/L perchloric acid VS
= 22.027 mg of $C_{15}H_{12}N_2$

Diphenyl phthalate $C_6H_4(COOC_6H_5)_2$ White crystalline powder.

Melting point: 71 - 76°C

Purity Related substances—Dissolve 0.06 g of diphenyl phthalate in 50 mL of chloroform and use this solution as the sample solution. Proceed with 10 μL of the sample solution as directed in the Assay under Tolnaftate Solution: any peak other than the principal peak at the retention time of about 8 minutes and the peak of the solvent does not appear. Adjust the detection sensitivity so that the peak height of diphenyl phthalate obtained from 10 μL of the sample solution is 50 to 100% of the full scale, and the time span of measurement is about twice as long as the retention time of diphenyl phthalate after the solvent peak.

1,1-Diphenyl-4-pyperidino-1-butene hydrochloride for thin-layer chromatography $C_{21}H_{25}N.HCl$ To 1 g of diphenidole hydrochloride add 30 mL of 1 mol/L hydrochloric acid TS, and heat under a reflux condenser for 1 hour. After cooling, extract twice with 30 mL-portions of chloroform, combine the chloroform extracts, wash twice with 10 mL portions of water, and evaporate chloroform under reduced pressure. Recrystallize the residue from a mixture of diethyl ether and ethanol (95) (3:1), and dry in a desiccator (in vaccum, silica gel) for 2 hours. White crystals or crystalline powder.

Absorbance $E^{1\%}_{1\,cm}$ (250 nm): 386 - 446 (0.01 g, water, 1000 mL).

Melting point: 176 - 180°C

Content: not less than 99.0%. Assay—Dissolve about 0.2 g of 1,1-diphenyl-4-pyperidino-1-butene hydrochloride for thin-layer chromatography, previously weighed accurately, in 20 mL of acetic acid (100), add 20 mL of acetic anhydride, and titrate with 0.05 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L perchloric acid VS
= 16.395 mg of $C_{21}H_{25}N.HCl$

Dipotassium hydrogenphosphate K_2HPO_4 [K 9017, Special class]

Dipotassium hydrogenphosphate-citric acid buffer solution, pH 5.3 Mix 100 mL of 1 mol/L dipotassium hydrogenphosphate TS for buffer solution and 38 mL of 1 mol/L citric acid TS for buffer solution, and add water to make 200 mL.

1 mol/L Dipotassium hydrogenphosphate TS for buffer solution Dissolve 174.18 g of dipotassium hydrogenphosphate in water to make 1000 mL.

α,α′-Dipyridyl See 2,2′-bipyridyl.

Disodium chromotropate dihydrate $C_{10}H_6Na_2O_8S_2.2H_2O$ [K 8316, Special class] Preserve in light-resistant containers.

0.1 mol/L Disodium dihydrogen ethylenediamine tetraacetate TS Dissolve 37.2 g of disodium dihydrogen ethylenediamine tetraacetate dihydrate in water to make 1000 mL.

0.4 mol/L Disodium dihydrogen ethylenediamine tetraacetate TS, pH 8.5 Dissolve 18.6 g of disodium dihydrogen ethylenediamine tetraacetate dihydrate in about 800 mL of water, adjust to pH 8.5 with 8 mol/L sodium hydroxide TS, and add water to make 1000 mL.

Disodium dihydrogen ethylenediamine tetraacetate dihydrate $C_{10}H_{14}N_2Na_2O_8.2H_2O$ [K 8107, Special class]

0.1 mol/L Disodium ethylenediaminetetraacetate TS See 0.1 mol/L disodium dihydrogen ethylenediamine tetraacetate TS.

Disodium ethylenediaminetetraacetate See disodium dihydrogen ethylenediamine tetraacetate dihydrate.

Disodium ethylenediaminetetraacetate copper See coppor (II) disodium ethylenediamine tetraacetate tetrahydrate.

Disodium hydrogenphosphate Na_2HPO_4 [K 9020, Special class]

Disodium hydrogenphosphate-citric acid buffer solution, pH 3.0 Dissolve 35.8 g of disodium hydrogenphosphate 12-water in water to make 500 mL. To this solution add a solution of citric acid monohydrate (21 in 1000) to adjust the pH to 3.0.

Disodium hydrogenphosphate-citric acid buffer solution, pH 4.5 Dissolve 21.02 g of citric acid monohydrate in water to make 1000 mL, and adjust the pH to 4.5 with a solution prepared by dissolving 35.82 g of disodium hydrogenphophate 12-water in water to make 1000 mL.

Disodium hydrogenphosphate-citric acid buffer solution, pH 5.4 Dissolve 1.05 g of citric acid monohydrate and 2.92 g of disodium hydrogenphosphate 12-water in 200 mL of water, and adjust the pH with phosphoric acid or sodium hydroxide TS, if necessary.

Disodium hydrogenphosphate-citric acid buffer solution, pH 6.0 Dissolve 71.6 g of disodium hydrogenphosphate 12-water in water to make 1000 mL. To this solution add a solution, prepared by dissolving 21.0 g of citric acid monohydrate in water to make 1000 mL, until the pH becomes 6.0 (ratio of volume: about 63:37).

Disodium hydrogenphosphate-citric acid buffer solution for penicillium origin β-galactosidase, pH 4.5 Dissolve 71.6 g of disodium hydrogenphosphate 12-water in water to make 1000 mL, and adjust the pH to 4.5 with a solution prepared by dissolving 21.0 g of citric acid monohydrate in water to make 1000 mL (volume ratio: about 44:56).

Disodium hydrogenphosphate for pH determination Na_2HPO_4 [K 9020, for pH determination]

Disodium hydrogenphosphate TS Dissolve 12 g of disodium hydrogenphosphate 12-water in water to make 100 mL (1/3 mol/L).

0.05 mol/L Disodium hydrogenphosphate TS Dissolve 7.0982 g of disodium hydrogenphosphate in water to make 1000 mL.

0.5 mol/L Disodium hydrogenphosphate TS Dissolve 70.982 g of disodium hydrogenphosphate in water to make 1000 mL.

Disodium hydrogenphosphate 12-water $Na_2HPO_4.12H_2O$ [K 9019, Special class]

Disodium 1-nitroso-2-naphthol-3,6-disulfonate $C_{10}H_5NNa_2O_8S_2$ [K 8714, Special class]

Dissolved acetylene C_2H_2 [K 1902]

Distigmine bromide for assay [Same as the monograph Distigmine Bromide. It contains not less than 99.0% of distigmine bromide ($C_{22}H_{32}Br_2N_4O_4$), calculated on the anhydrous basis.]

Distilled water for injection [Same as the monograph in Part II, Water for Injection. Prepared by distillation.]

2,6-Di-*tert*-butylcresol $[(CH_3)_3C]_2C_6H_2(CH_3)OH$
A white, crystalline powder. Freely soluble in ethanol (95).
Melting point: 69 - 71°C
Residue on ignition: not more than 0.05%.

2,6-Di-*tert*-butylcresol TS Dissolve 0.1 g of 2,6-di-*tert*-butylcresol in ethanol (95) to make 10 mL.

2,6-Di-*tert*-butyl-*p*-cresol See 2,6-di-*tert*-butylcresol.

2,6-Di-*tert*-butyl-*p*-cresol TS See 2,6-di-*tert*-butylcresol TS.

1,3-Di (4-pyridyl) propane $C_{13}H_{14}N_2$ A pale yellow powder.
Melting point: 61 - 62°C
Water: less than 0.1%.

1,1′-[3,3′-Dithiobis(2-methyl-1-oxopropyl)]-L-diproline $C_{18}H_{28}N_2O_6S_2$ White, crystals or crystalline powder. Sparingly soluble in methanol, and practically insoluble in water.
Identification—Determine the infrared absorption spectrum of 1,1′-[3,3′-dithiobis(2-methyl-1-oxopropyl)]-L-diproline according to potassium bromide disk method under the Infrared Spectrophotometry: it exhibits absorption at the wave numbers of about 2960 cm^{-1}, 1750 cm^{-1}, 1720 cm^{-1}, 1600 cm^{-1}, 1480 cm^{-1}, 1450 cm^{-1} and 1185 cm^{-1}.
Purity Related substances—Dissolve 0.10 g of 1,1′-[3,3′-dithiobis (2-methyl-1-oxopropyl)]-L-diproline in exactly 10 mL of methanol. Perform the test with this solution as directed in the Purity (3) under Captopril: any spot other than the principal spot at the *R*f value of about 0.2 does not appear.
Content: not less than 99.0%. Assay—Weigh accurately about 0.3 g of 1,1′-[3,3′-dithiobis (2-methyl-1-oxopropyl)]-L-diproline, dissolve in 20 mL of methanol, add 50 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS until the color of the solution changes from yellow through bluish green to blue (indicator: 3 drops of bromothymol blue TS). Perform a blank determination in the same manner, and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 21.628 mg of $C_{18}H_{28}N_2O_6S_2$

Dithiothreitol $C_4H_{10}O_2S_2$ Crystals.
Melting point: about 42°C

Dithizone $C_6H_5NHNHCSN{:}NC_6H_5$ [K 8490, Special class]

Dithizone solution for extraction Dissolve 30 mg of dithizone in 1000 mL of chloroform, and add 5 mL of ethanol (95). Store in a cold place. Before use, shake a suitable volume of the solution with one-half of its volume of diluted nitric acid (1 in 100), and use the chloroform layer after discarding the water layer.

Dithizone TS Dissolve 25 mg of dithizone in ethanol (95) to make 100 mL. Prepare before use.

Dopamine hydrochloride for assay $C_8H_{11}NO_2.HCl$ [Same as the monograph Dopamine hydrochloride. When dried, it contains not less than 99.0% of dopamine hydrochloride ($C_8H_{11}NO_2.HCl$).

Dragendorff's TS Dissolve 0.85 g of bismuth subnitrate in 10 mL of acetic acid (100) and 40 mL of water with vigorous shaking (solution A). Dissolve 8 g of potassium iodide in 20 mL of water (solution B). Immediately before use, mix equal volumes of solution A, solution B and acetic acid (100). Store solution A and solution B in light-resistant containers.

Dragendorff's TS for spraying Add 20 mL of diluted acetic acid (31) (1 in 5) to 4 mL of a mixture of equal volumes of solution A and solution B of Dragendorff's TS. Prepare before use.

Dried sodium carbonate Na_2CO_3 [Same as the namesake monograph in Part II]

Dydrogesterone for assay $C_{21}H_{28}O_2$ [Same as the monograph Dydrogesterone. When dried, it contains not less than 99.0% of $C_{21}H_{28}O_2$]

EMB plate medium Melt eosin methylene blue agar medium by heating, and cool to about 50°C. Transfer about 20 mL of this medium to a Petri dish, and solidify horizontally. Place the dish with the cover slightly opened in the incubator to evaporate the inner vapor and water on the plate.

Emetine hydrochloride for component determination $C_{29}H_{40}N_2O_4.2HCl.xH_2O$ A white or light-yellow crystalline powder. Soluble in water.
Melting point: about 250°C [with decomposition, after drying in a desiccator (reduced pressure below 0.67 kPa, phosphorus (V) oxide, 50°C) for 5 hours].
Absorbance $E^{1\%}_{1\,cm}$ (283 nm) : 113 - 125 (0.01 g, diluted methanol (1 in 2), 400 mL) [after drying in a desiccator (reduced pressure below 0.67 kPa, phosphorus (V) oxide, 50°C) for 5 hours.]
Purity Related substances—Dissolve 0.01 g of emetine hydrochloride 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 (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 operating conditions. Determine the peak areas from both solutions by the automatic integration method: the total area of peaks other than emetine from the sample solution is not larger than the peak of emetine from the standard solution (1).
Operating conditions
Proceed the operating conditions in the Component determination under Ipecac except the 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 sensitivity so that the peak area of emetine obtained from 10 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of emetine obtained 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 emetine after the soluent peak.

Endo's medium Melt 1000 mL of the ordinary agar medium by heating in a water bath, and adjust the pH to between 7.5 and 7.8. Add 10 g of lactose monohydrate previously dissolved in a small quantity of water, mix thoroughly, and add 1 mL of fuchsin-ethanol (95) TS. After cooling to about 50°C, add dropwise a freshly prepared solution of sodium bisulfite (1 in 10) until a light red color develops owing to reducing fuchsin, requiring about 10 to 15 mL of a solution of sodium sulfite heptahydrate (1 in 10). Dispense the mixture, and sterilize fractionally on each of three successive days for 15 minutes at 100°C.

Endo's plate medium Melt Endo's medium by heating, and cool to about 50°C. Transfer about 20 mL of this medium to a Petri dish, and solidify horizontally. Place the dishes with the cover slightly opened in the incubator to evaporate the inner vapor and water on the surface of the agar.

Enzyme TS The supernatant liquid is obtained as follows: To 0.3 g of an enzyme preparation potent in amylolytic and phosphorolytic activities, obtained from *Aspergillus oryzae*, add 10 mL of water and 0.5 mL of 0.1 mol/L hydrochloric acid TS, mix vigorously for a few minutes, and centrifuge. Prepare before use.

Eosin See eosin Y.

Eosin Y $C_{20}H_6Br_4Na_2O_5$ [K 8651: 1988, First class]

Eosin methylene blue agar medium Dissolve by boiling 10 g of casein peptone, 2 g of dipotassium hydrogenphosphate and 25 to 30 g of agar in about 900 mL of water. To this mixture add 10 g of lactose monohydrate, 20 mL of a solution of eosin Y(1 in 50), 13 mL of a solution of methylene blue (1 in 200) and warm water to make 1000 mL. Mix thoroughly, dispense, sterilize by autoclaving at 121°C for not more than 20 minutes, and cool quickly by immersing in cold water, or sterilize fractionally on each of three successive days for 30 minutes at 100°C.

Ephedrine hydrochloride $C_{10}H_{15}NO.HCl$ [Same as the namesake monograph]

Ephedrine hydrochloride for assay $C_{10}H_{15}NO.HCl$ [Same as the namesake monograph meeting the following additional specifications.]

Purity Related substances—Dissolve 0.05 g of ephedrine hydrochloride for assay in 50 mL of the mobile phase and use this solution as the sample solution. Pipet 1 mL of this solution and add the mobile phase to make exactly 100 mL, and use this solution as the standard solution (1). Perform the test with 10 μL 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 ephedrine from the sample solution is not larger than the peak area of ephedrine from the standard solution (1).

Operating conditions

Proceed the operating conditions in the Assay under Ephedra Herb 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 ephedrine obtained from 10 μL of the standard solution (2) can be measured by the automatic integration method, and the peak height of ephedrine 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 ephedrine after the solvent peak.

Eriochrome black T $C_{20}H_{12}N_3NaO_7S$ [K 8736, Special class]

Eriochrome black T-sodium chloride indicator Mix 0.1 g of eriochrome black T and 10 g of sodium chloride, and triturate until the mixture becomes homogeneous.

Eriochrome black T TS Dissolve 0.3 g of eriochrome black T and 2 g of hydroxylammonium chloride in methanol to make 50 mL. Use within 1 week. Preserve in light-resistant containers.

Essential oil Same as the essential oil under the monograph.

Etacrynic acid for assay [Same as the monograph Etacrynic acid. When dried, it contains not less than 99.0% of etacrynic acid ($C_{13}H_{12}Cl_2O_4$).]

Ethanol See ethanol (95).

Ethanol, aldehyde-free Transfer 1000 mL of ethanol (95) to a glass-stoppered bottle, add the solution prepared by dissolving 2.5 g of lead (II) acetate trihydrate in 5 mL of water, and mix thoroughly. In a separate container, dissolve 5 g of potassium hydroxide in 25 mL of warm ethanol (95), cool, and add this solution gently, without stirring, to the first solution. After 1 hour, shake this mixture vigorously, allow to stand overnight, decant the supernatant liquid, and distil the ethanol.

Ethanol, dehydrated See ethanol (99.5).

Ethanol, dilute To 1 volume of ethanol (95) add 1 volume of water. It contains 47.45 to 50.00 vol% of C_2H_5OH.

Ethanol, diluted Prepare by diluting ethanol (99.5).

Ethanol for disinfection [Same as the namesake monograph in Part II]

Ethanol for gas chromatography Use ethanol prepared by distilling ethanol (99.5) with iron (II) sulfate heptahydrate. Preserve in containers, in which the air has been displaced with nitrogen, in a dark, cold place.

Ethanol-free chloroform See chloroform, ethanol-free.

Ethanol-isotonic sodium chloride solution To 1 volume of ethanol (95) add 19 volumes of isotonic sodium chloride solution.