1-Naphthol $C_{10}H_7OH$ [K 8698, Special class] Preserve in light-resistant containers.

2-Naphthol $C_{10}H_7OH$ [K 8699, Special class] Preserve in light-resistant containers.

α-Naphthol See 1-naphthol.

β-Naphthol See 2-naphthol.

***p*-Naphtholbenzein** $C_{27}H_{20}O_3$ [K 8693, Special class]

α-Naphtholbenzein See *p*-naphtholbenzein.

***p*-Naphtholbenzein TS** Dissolve 0.2 g of *p*-naphtholbenzein in acetic acid (100) to make 100 mL.

Purity Clarity and color of solution—Dissolve 0.1 g of *p*-naphtholbenzein in 100 mL of ethanol (95): the solution is red in color and clear.

Sensitivity—Add 100 mL of freshly boiled and cooled water to 0.2 mL of a solution of *p*-naphtholbenzein in ethanol (95) (1 in 1000), and add 0.1 mL of 0.1 mol/L sodium hydroxide VS: a green color develops. Add subsequently 0.2 mL of 0.1 mol/L hydrochloric acid VS: the color of the solution changes to yellow-red.

α-Naphtholbenzein TS See *p*-naphtholbenzein TS.

1-Naphthol TS Dissolve 6 g of sodium hydroxide and 16 g of anhydrous sodium carbonate in water to make 100 mL. In this solution dissolve 1 g of 1-naphthol. Prepare before use.

2-Naphthol TS Dissolve 1 g of 2-naphthol in sodium carbonate TS to make 100 mL. Prepare before use.

α-Naphthol TS See 1-naphthol TS.

β-Naphthol TS See 2-naphthol TS.

1-Naphthylamine $C_{10}H_7NH_2$ [K 8692, Special class] Preserve in light-resistant containers.

α-Naphthylamine See 1-naphthylamine.

***N*-(1-Naphthyl)-*N'*-diethylethylenediamine oxalate** See *N*, *N*-diethyl-*N'*-1-naphthylethylenediamine oxalate.

***N*-(1-Naphthyl)-*N'*-diethylethylenediamine oxalate-acetone TS** See *N*, *N*-diethyl-*N'*-1-naphthylethylenediamine oxalate-acetone TS.

***N*-(1-Naphthyl)-*N'*-diethylethylenediamine oxalate TS** See *N*, *N*-diethyl-*N'*-1-naphthylethylenediamine oxalate TS.

Naphthylethylenediamine TS Dissolve 0.1 g of *N*-1-naphthylethylenediamine dihydrochloride in water to make 100 mL. Prepare before use.

***N*-1-Naphthylethylenediamine dihydrochloride** $C_{10}H_7NHCH_2CH_2NH_2.2HCl$ [K8197, Special class]

Naringin for thin-layer chromatography $C_{27}H_{32}N_{14}.2H_2O$ White crystals or crystalline powder. Freely soluble in ethanol (95) and in acetone, and slightly soluble in water. Melting point: about 170°C (with decomposition).

Optical rotation $[\alpha]_D^{20}$: −87 – −93° (0.1 g, ethanol (95), 10 mL, 100 mm).

Purity Related substances—Proceed with 10 μL of a solution, prepared by dissolving 10 mg of naringin for thin-layer chromatography in 10 mL of ethanol (95), as directed in the Identificaiton under Bitter Orange Peel: any spot other than the principal spot at the *Rf* value of about 0.4 does not appear.

Neutral alumina containing 4% of water Take 50 g of neutral alumina for column chromatography, previously dried at 105°C for 2 hours, in a tight container, add 2.0 mL of water, shake well to make homogeneous, and allow to stand for more than 2 hours.

Neutral alumina for chromatography Prepared for chromatography (75 – 180 μm in particle diameter).

Neutral alumina for column chromatography Prepared for column chromatography.

Neutral detergent Synthetic detergent containing anionic or non-ionic surfactant, and pH of its 0.25% solution is between 6.0 and 8.0. Dilute to a suitable concentration before use.

Neutralized ethanol See ethanol, neutralized.

Neutral red $C_{15}H_{17}N_4Cl$ [K 8729: 1992, Special class]

Neutral red TS Dissolve 0.1 g of neutral red in acetic acid (100) to make 100 mL.

Nicardipine hydrochloride for assay $C_{26}H_{29}N_3O_6.HCl$ [Same as the monograph Nicardipine Hydrochloride. When dried, it contains not less than 99.0% of nicardipine hydrochloride ($C_{26}H_{29}N_3O_6.HCl$).]

Nickel for thermal analysis [K 9062 (Nickel), Special class. Content: not less than 99.99%]

Nicomol for assay $C_{34}H_{32}N_4O_9$ [Same as the monograph Nicomol. When dried, it contains not less than 99.0% of $C_{34}H_{32}N_4O_9$].

Nicotinamide $C_6H_6N_2O$ [Same as the namesake monograph]

Nicotinamide adenine dinucleotide See β-nicotinamide-adenine dinucleotide, oxidized form.

β-Nicotinamide-adenine dinucleotide, oxidized form $C_{21}H_{27}N_7O_{14}P_2$ [K 9802]

Content: not less than 94.5%. Assay—Weigh accurately about 0.025 g of β-nicotinamide-adenine dinucleotide, oxidized form, and dissolve in water to make exactly 25 mL. Pipet 0.2 mL of this solution, add 0.1 mol/L phosphate buffer solution, pH 7.0, to make exactly 10 mL, and use this solution as the sample solution. Determine the absorbances, A_T and A_B, of the sample solution and 0.1 mol/L phosphate buffer solution, pH 7.0, at 260 nm as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank.

$$\text{Amount (mg) of } C_{21}H_{27}N_7O_{14}P_2 = \frac{0.6634 \times 10}{17.6 \times 0.20} \times (A_T - A_B) \times 25$$

Nicotinamide adenine dinucleotide TS See β-nicotinamide-adenine dinucleotide TS.

β-Nicotinamide adenine dinucleotide TS Dissolve 40 mg of β-nicotinamide adenine dinucleotide, oxidized form in 10 mL of water. Prepare before use.

Nifedipine $C_{17}H_{18}N_2O_6$ [Same as the namesake monograph]

Ninhydrin $C_9H_6O_4$ [K 8870, Special class]

Ninhydrin TS Dissolve 0.2 g of ninhydrin in water to make 10 mL. Prepare before use.

Ninhydrin-L-ascorbic acid TS Dissolve 0.25 g of ninhydrin and 0.01 g of L-ascorbic acid in water to make 50 mL. Prepare before use.

Ninhydrin-butanol TS Dissolve 0.3 g of ninhydrin in 100 mL of 1-butanol, and add 3 mL of acetic acid (100).

Ninhydrin-citric acid-acetic acid TS Dissolve 70 g of citric acid monohydrate in 500 mL of water, add 58 mL of acetic acid (100), 70 mL of a solution of sodium hydroxide (21 in 50) and water to make 1000 mL. In 100 mL of this solution dissolve 0.2 g of ninhydrin.

Ninhydrin-stannous chlorid TS See ninhydrin-tin (II) chloride TS.

Ninhydrin-sulfuric acid TS Dissolve 0.1 g of ninhydrin in 100 mL of sulfric acid. Prepare before use.

Ninhydrin-tin (II) chloride TS Dissolve 21.0 g of citric acid in water to make 200 mL, adjust the pH to 5.6 ± 0.2 by adding sodium hydroxide TS, add water to make 500 mL, and dissolve 1.3 g of tin (II) chloride. To 50 mL of the solution, add 50 mL of a 2-methoxethanol solution of ninhydrin (2 in 50). Prepare before use.

0.2% Ninhydrin-water saturated 1-butanol TS Dissolve 2 g of ninhydrin in 1-butanol saturated with water to make 1000 mL.

Nitric acid HNO_3 [K 8541, Special class, Concentration: 69 - 70%, Density: about 1.42 g/mL]

Nitric acid, dilute Dilute 10.5 mL of nitric acid with water to make 100 mL (10%).

Nitric acid, fuming [K 8739, Special class, Concentration: not less than 97%, Density: 1.52 g/mL]

2,2′,2″-Nitrilotrisethanol $(CH_2CH_2OH)_3N$ [K 8663, Special class]

2,2′,2″-Nitrilotrisethanol buffer solution, pH 7.8 Dissolve 149.2 g of 2,2′,2″-nitrilotrisethanol in about 4500 mL of water, adjust to pH 7.8 with 4 mol/L hydrochloric acid, and add water to make 5000 mL.

***p*-Nitroaniline** See 4-nitroaniline.

4-Nitroaniline $O_2NC_6H_4NH_2$ [K 8708, *p*-Nitroaniline, Special class]

***p*-Nitroaniline-sodium nitrite TS** See 4-nitroaniline-sodium nitrite TS.

4-Nitroaniline-sodium nitrite TS To 90 mL of a solution of 0.3 g of 4-nitroaniline in 100 mL of 10 mol/L hydrochloric acid TS add 10 mL of a solution of sodium nitrite (1 in 20), and mix well. Prepare before use.

***o*-Nitrobenzaldehyde** See 2-nitrobenzaldehyde.

2-Nitrobenzaldehyde $O_2NC_6H_4CHO$ Pale yellow crystals or crystalline powder.
Melting point: 42 - 44°C

Nitrobenzene $C_6H_5NO_2$ [K 8723, Special class]

***p*-Nitrobenzenediazonium chloride TS** See 4-nitrobenzenediazonium chloride TS.

4-Nitrobenzenediazonium chloride TS Dissolve 1.1 g of 4-nitroaniline in 1.5 mL of hydrochloric acid, add 1.5 mL of water, and then add a solution prepared by dissolving 0.5 g of sodium nitrite in 5 mL of water, while cooling in an ice bath. Prepare before use.

***p*-Nitrobenzenediazonium chloride TS for spraying** See 4-nitrobenzenediazonium chloride TS for spraying.

4-Nitrobenzenediazonium chloride TS for spraying Dissolve 0.4 g of 4-nitroaniline in 60 mL of 1 mol/L hydrochloric acid TS, and add, while cooling in an ice bath, sodium nitrite TS until the mixture turns potassium iodide-starch paper to blue in color. Prepare before use.

***p*-Nitrobenzenediazonium fluoroborate** See 4-nitrobenzenediazonium fluoroborate.

4-Nitrobenzenediazonium fluoroborate
$O_2NC_6H_4N_2BF_4$ Pale yellowish white, almost odorless powder. Freely soluble in dilute hydrochloric acid, slightly soluble in water, and very slightly solute in ethanol (95) and in chloroform.
Melting point: about 148°C (with decomposition).
Identification—Add 1 mL each of a solution of phenol (1 in 1000) and sodium hydroxide TS to 10 mL of a solution of 4-nitrobenzenediazonium fluoroborate (1 in 1000): a red color develops.
Loss on drying: not more than 1.0% (1 g, silica gel, 2 hours).

***p*-Nitrobenzoyl chloride** See 4-nitrobenzoyl chloride.

4-Nitrobenzoyl chloride $O_2NC_6H_4COCl$ Light yellow crystals.
Melting point: 70 - 74°C
Content: not less than 98.0%. Assay—Weigh accurately about 0.5 g of 4-nitrobenzoyl chloride, add an excess of silver nitrate-ethanol TS, and boil under a reflux condenser for 1 hour. After cooling, filter the precipitate, wash with water, dry at 105°C to constant mass, and weigh. The mass of 4-nitrobenzoyl chloride, multiplied by 1.107, represents the mass of 4-nitrobenzoyl chloride ($C_7H_4ClNO_3$).

***p*-Nitrobenzyl chloride** See 4-nitrobenzyl chloride.

4-Nitrobenzyl chloride $O_2NC_6H_4CH_2Cl$ Light yellow crystals or crystalline powder. Soluble in ethanol (95).
Melting point: 71 - 73°C
Content: not less than 98.0%. Assay—Weigh accurately about 0.5 g of 4-nitrobenzyl chloride, add 15 mL of a solution prepared by dissolving 4 g of silver nitrate in 10 mL of water and adding ethanol (95) to make 100 mL, and heat on a water bath under a reflex condensor for 1 hour. After cooling, filter the precipitate with a glass filter, wash with water, dry at 105°C to constant mass, and weigh. The mass of the precipitate represents the amount of silver chloride (AgCl: 143.32).

Amount (mg) of 4-nitrobenzyl chloride
= amount (mg) of silver chloride (AgCl: 143.32) × 1.197

4-(4-Nitrobenzyl)pyridine $C_{12}H_{10}N_2O_2$ Pale yellow, crystalline powder. Freely soluble in acetone, and soluble in ethanol (95).
Melting point: 69 - 71°C

Nitrogen [Same as the namesake monograph in Part II]

Nitrogen monoxide NO A colorless gas. Prepare by

adding sodium nitrite TS to a solution of iron (II) sulfate heptahydrate in dilute sulfuric acid. Nitrogen monoxide from a metal cylinder may be used.

Nitromethane CH_3NO_2 [K 9523, Special class]

***o*-Nitrophenol** $C_6H_5NO_3$ [K 8719, Special class]

***o*-Nitrophenyl-β-D-galactopyranoside** See 2-nitrophenyl-β-D-galactopyranoside.

2-Nitrophenyl-β-D-galactopyranoside $C_{12}H_{15}NO_8$ White crystalline powder. Odorless. It is sparingly soluble in water, slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

Melting point: 193 - 194°C

Purity Clarity and color of solution—A solution of 2-nitrophenyl-β-D-galactopyranoside (1 in 100) is clear and colorless.

Loss on drying: not more than 0.1% (0.5 g, 105°C, 2 hours).

Content: not less than 98.0%. Assay—Weigh accurately about 0.05 g of 2-nitrophenyl-β-D-galactopyranoside, previously dried, dissolve in water to make exactly 100 mL. Pipet 20 mL of this solution, and add water to make exactly 50 mL. Determine the absorbance, A, of this solution at 262 nm as directed under the Ultraviolet-visible Spectrophotometry.

$$\text{Amount (mg) of 2-nitrophenyl-}\beta\text{-D-galactopyranoside} = \frac{A}{133} \times 25{,}000$$

1-Nitroso-2-naphthol $C_{10}H_7NO_2$ [K 8713, Special class]

1-Nitroso-2-naphthol TS Dissolve 0.06 g of 1-nitroso-2-naphthol in 80 mL of acetic acid (100), and add water to make 100 mL.

α-Nitroso-β-naphthol See 1-nitroso-2-naphthol.

α-Nitroso-β-naphthol TS See 1-nitroso-2-naphthol TS.

Nitrous oxide N_2O Colorless and odorless gas. Use nitrous oxide from a metal cylinder.

NN Indicator Mix 0.5 g of 2-hydroxy-1-(2′-hydroxy-4′-sulfo-1′-naphthylazo)-3-naphthoic acid with 50 g of anhydrous sodium sulfate, and triturate until the mixture becomes homogeneous.

***n*-Octadecane** $C_{18}H_{38}$ Colorless or white solid at ordinary temperature.

Purity Clarity of solution—A solution of *n*-octadecane in chloroform (1 in 25) is clear.

Octadecylsilanized polyvinyl alcohol gel polymer for liquid chromatography Prepared for liquid chromatography.

Octadecylsilanized silica gel for liquid chromatography Prepared for liquid chromatography.

Octadecylsilanized silica gel for pretreatment Prepared for pretreatment.

Octadecylsilanized silicone polymer coated silica gel for liquid chromatography Prepared for liquid chromatography.

***n*-Octane** C_8H_{18}

Specific gravity d_4^{20}: 0.700 - 0.705

Purity—Perform the test with 2 μL of *n*-octane as directed under the Gas Chromatography according to the conditions in the Assay under Hydroxypropylmethylcellulose 2208. Measure each peak area by the automatic integration method, and calculate the amount of *n*-octane by the area percentage method: not less than 99.0%.

Octane, iso A colorless liquid. Practically insoluble in water. Miscible with diethyl ether and with chloroform.

Purity—Determine the absorbances of isooctane at 230 nm, 250 nm and 280 nm as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank solution: these values are not more than 0.050, 0.010 and 0.005, respectively.

1-Octanol $CH_3(CH_2)_6CH_2OH$ [K 8213, Special class]

Octyl alcohol See 1-octanol.

***n*-Octylbenzen** $C_{14}H_{22}$ Clear and colorless liquid, having a characteristic odor.

Specific gravity d_4^{20}: 0.854 - 0.863

Distillation test: 263 - 265°C, not less than 95 vol%.

Octylsilanized silica gel for liquid chromatography Prepared for liquid chromatography.

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

Orcine $C_7H_8O_2$ White to light red-brown crystals or crystalline powder, having an unpleasant, sweet taste. It turns to red in color when oxidized in air. Soluble in water, in ethanol (95), and in diethyl ether.

Meting point: 107 - 111°C

Orcine-ferric chloride TS See orcine-iron (III) chloride TS.

Orcine-iron (III) chloride TS Dissolve 10 mg of orcine in 1 mL of a solution of iron (III) chloride hexahydrate in hydrochloric acid (1 in 1000). Prepare before use.

Ordinary agar medium Dissolve 25 to 30 g of agar in 1000 mL of ordinary broth with the aid of heat, add water to make up for the loss, adjust the pH to between 6.4 and 7.0, and filter. Dispense the filtrate, and sterilize by autoclaving. When powdered agar is used, 15 to 20 g of it is dissolved.

Ordinary broth Dissolve 5 g of beef extract and 10 g of peptone in 1000 mL of water by gentle heating. Adjust the pH of the mixture between 6.4 and 7.0 after sterilization, cool, add water to make up for the loss, and filter. Sterilize the filtrate by autoclaving for 30 minutes at 121°C.

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

Oxalic acid See oxalic acid dihydrate.

Oxalic acid dihydrate $H_2C_2O_4.2H_2O$ [K 8519, Special class]

Oxalic acid TS Dissolve 6.3 g of oxalic acid dihydrate in water to make 100 mL (0.5 mol/L).

Oxycodone hydrochloride for assay $C_{18}H_{21}NO_4.HCl.3H_2O$ [Same as the monograph Oxyco-

done Hydrochloride. It contains not less than 99.0% of oxycodone hydrochloride ($C_{18}H_{21}NO_4$.HCl), calculated on the anhydrous basis.]

Oxygen O_2 [K 1101]

8-Oxyquinoline See 8-quinolinol.

2-Oxy-1-(2′-oxy-4′-sulfo-1′-naphthylazo)-3-naphthoic acid See 2-hydroxy-1-(2′-hydroxy-4′-sulfo-1′-naphthylazo)-3-naphthoic acid.

Paeoniflorin for thin-layer chromatography $C_{23}H_{28}O_{11}.nH_2O$ Colorless, odorless powder. Freely soluble in water and in methanol, and not dissolves in diethyl ether.

Melting point: 123 - 125°C

Purity Related substances—Dissolve 1.0 mg of paeoniflorin for thin layer chromatography in exactly 1 mL of methanol. Perform the test with 20 μL of this solution as directed in the Identification (2) under Peony Root: any spot other than the principal spot at the *R*f value of about 0.3 does not appear.

Palladium chloride See palladium (II) chloride.

Palladium chloride TS See palladium (II) chloride TS.

Palladium (II) chloride $PdCl_2$ [K 8154, Special class]

Palladium (II) chloride TS Dissolve 0.2 g of palladium (II) chloride in 500 mL of 0.25 mol/L sulfuric acid TS, by heating if necessary, cool, and add 0.25 mol/L sulfuric acid TS to make 1000 mL.

Palmatin chloride $C_{21}H_{22}ClNO_4.nH_2O$ Yellow-brown crystalline powder.

Purity—Dissolve 1 mg of palmatin chloride in methanol to make exactly 10 mL, and use this solution as the sample solution. Proceed with 20 μL of the sample solution as directed under the Liquid Chromatography according to the operating conditions in the Assay under Phellodendron Bark. The summed area of the peaks other than palmatin from the sample solution is not larger than 1/10 of the total area except the area of solvent peak.

Palmitic acid for gas chromatography $C_{16}H_{32}O_2$ [K 8756, Special class]

Papaverine hydrochloride $C_{20}H_{21}NO_4$.HCl [Same as the namesake monograph]

Papaverine hydrochloride for assay $C_{20}H_{21}NO_4$.HCl [Same as the monograph Papaverine Hydrochloride. When dried, it contains not less than 99.0% of papaverine hydrochloride ($C_{20}H_{21}NO_4$.HCl).]

Paraffin [Same as the namesake monograph in Part II]

Paraffin, liquid [Same as the monograph in Part II Light Liquid Paraffin]

Parahydroxybenzoic acid $C_7H_6O_3$ White crystals.

Melting point: 212 - 216°C

Content: not less than 98.0 %. Assay—Weigh accurately about 0.7 g of parahydroxybenzoic acid, dissolve in 50 mL of acetone, add 100 mL of water, and titrate with 0.5 mol/L sodium hydroxide VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.5 mol/L sodium hydroxide VS
= 69.06 mg of $C_7H_6O_3$

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

Pentane $CH_3(CH_2)_3CH_3$ Clear and colorless liquid.

Specific gravity d_{20}^{20}: 0.620 - 0.650

Distilling range: 35.5 - 37°C, not less than 98 vol%.

Peonol for component determination Use peonol for thin-layer chromatography meeting the following additional specifications.

Absorbance $E_{1\,cm}^{1\%}$ (274 nm): 853 - 934 [0.005 g after drying in a desiccator (calcium chloride for drying) for 1 hour or more, methanol, 1000 mL].

Purity Related substances—Dissolve 0.5 mg of peonol 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 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 conditions, and measure each peak area of these solutions by the automatic integration method: the total area of the peaks other than peonol from the sample solution is not larger than the peak area of peonol from the standard solution (1).

Operating conditions

Proceed the operating conditions in the Component determination under Moutan Bark 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 peonol obtained from 10 μL of the standard solution (2) can be measured, and the peak height of peonol 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 peonol after the solvent peak.

Peonol for thin-layer chromatography $C_9H_{10}O_3$ White, crystals or crystalline powder, having a specific odor. Freely soluble in methanol and in diethyl ether, and slightly soluble in water.

Melting point: about 50°C

Purity Related substances—Dissolve 1.0 mg of peonol for thin-layer chromatography in exactly 1 mL of methanol, and perform with 10 μL of this solution as directed in the Identification under Moutan Bark: any spot other than the principal spot at the *R*f value of near 0.5 does not appear.

Peptone Prepared for microbial test.

Peptone, animal tissue Prepared for microbial test.

Peptone, casein Grayish yellow powder, having a characteristic but not putrescent odor. It dissolves in water, but not in ethanol (95) and in diethyl ether.

Loss on drying: not more than 7% (0.5 g, 105°C, constant mass).

Residue on ignition: not more than 15% (0.5 g).

Degree of digestion—Dissolve 1 g of casein peptone in 10 mL of water, and perform the following test using this solution as the sample solution:

(1) Overlay 1 mL of the sample solution with 0.5 mL of a mixture of 1 mL of acetic acid (100) and 10 mL of dilute ethanol: no ring or precipitate forms at the junction of the