two liquids, and on shaking, no turbidity results.

(2) Mix 1 mL of the sample solution with 4 mL of a saturated solution of zinc sulfate heptahydrate: a small quantity of precipitate is produced (proteoses).

(3) Filter the mixture of (2), and to 1 mL of the filtrate add 3 mL of water and 4 drops of bromine TS: a red-purple color is produced.

Nitrogen content: not less than 10% (105°C, constant mass, after drying, according to the Nitrogen Determination).

Peptone, gelatin Prepared for microbial test.

Peptone, soybean Prepared for microbial test.

Perchloric acid $HClO_4$ [K 8223, Special class, Density: about 1.67 g/mL. Concentration: 70 - 72%]

Perchloric acid-dehydrated ethanol TS See perchloric acid-ethanol TS.

Perchloric acid-ethanol TS Add cautiously 25.5 mL of perchloric acid to 50 mL of ethanol (99.5), cool, and add ethanol (99.5) to make 100 mL (3 mol/L).

Peroxidase Obtained from horse-radish. A red-brown powder. It is freely soluble in water. It contains about 250 units per mg. One unit indicates an amount of the enzyme which produces 1 mg of purpurogallin in 20 seconds at 20°C and pH 6.0, from pyrogallol and hydrogen peroxide (30) used as the substrate.

Peroxidase-labeled bradykinin A solution of horseradish origin peroxidase-binding bradykinin in gelatin-phosphate buffer solution, pH 7.0. A colorless to light brown clear solution.

Peroxidase-labeled bradykinin TS To 0.08 mL of peroxidase-labeled bradykinin, 8 mg of sodium tetraborate decahydrate, 8 mg of bovine serum albumin and 0.8 mL of gelatin-phosphate buffer solution, pH 7.0 add water to make 8 mL, and lyophilize. Dissolve this in 8 mL of water. Prepare before use.

Perphenazine maleate for assay [Same as the monograph Perphenazine Maleate. When dried, it contains not less than 99.0% of perphenazine maleate ($C_{21}H_{26}ClN_3OS.2C_4H_4O_4$).]

Pethidine hydrochloride for assay $C_{15}H_{21}NO_2.HCl$ [Same as the monograph Pethidine Hydrochloride. When dried, it contains not less than 99.0% of pethidine hydrochloride $C_{15}H_{21}NO_2.HCl$.]

Petrolatum [Same as the monograph in Part II Yellow Petrolatum or White Petrolatum]

Petroleum benzine [K 8594, Special class]

Petroleum ether [K 8593, Special class]

Phenacetin $C_{10}H_{13}NO_2$ [Same as the namesake monograph]

***o*-Phenanthroline** See 1,10-phenanthroline monohydrate.

***o*-Phenanthroline hydrochloride** See 1,10-phenanthrolium chloride monohydrate.

1,10-Phenanthroline monohydrate $C_{12}H_8N_2.H_2O$ [K 8789, Special class]

***o*-Phenanthroline TS** See 1,10-phenanthroline TS.

1,10-Phenanthroline TS Dissolve 0.15 g of 1,10-phenanthroline monohydrate in 10 mL of a freshly prepared ferrous sulfate solution (37 in 2500) and 1 mL of dilute sulfuric acid. Preserve in tightly stoppered containers.

1,10-Phenanthrolinium chloride monohydrate $C_{12}H_8N_2.HCl.H_2O$ [K 8202, Special class]

Phenethylamine hydrochloride $C_6H_5CH_2CH_2NH_2.HCl$ White crystals or crystlline powder.

Melting point: 220 - 225°C

Phenobarbital sodium $C_{12}H_{11}N_2NaO_3$ [Same as the namesake monograph]

Phenol C_6H_5OH [K 8798, Special class]

Phenol for assay C_6H_5OH [K 8798, Special class]

Phenol-hydrochloric acid TS Dissolve 0.2 g of phenol in 10 mL of 6 mol/L hydrochloric acid TS.

Phenolphthalein $C_{20}H_{14}O_4$ [K 8799, Special class]

Phenolphthalein-thymol blue TS Solution A: Dissolve 0.1 g of phenolphthalein in diluted ethanol (99.5) (4 in 5). Solution B: Dissolve 0.1 g of thymol blue in 50 mL of a mixture of ethanol and dilute sodium hydroxide TS, add water to make 100 mL. Mix 2 volumes of solution A and 3 volumes of solution B before use.

Phenolphthalein TS Dissolve 1 g of phenolphthalein in 100 mL of ethanol (95).

Phenol red $C_{19}H_{14}O_5S$ [K 8800, Special class]

Phenol red TS Dissolve 0.1 g of phenol red in 100 mL of ethanol (95), and filter if necessary.

Phenol-sodium nitroprusside TS See phenol-sodium pentacyanonitrosylferrate (III) TS.

Phenol-sodium pentacyanonitrosylferrate (III) TS Dissolve 5 g of phenol and 0.025 g of sodium pentacyanonitrosylferrate (III) dihydrate in sufficient water to make 500 mL. Preserve in a dark, cold place.

Phenolsulfonphthalein for assay $C_{19}H_{14}O_5S$ [Same as the monograph Phenolsulfonphthalein. When dried, it contains not less than 99.0% of phenolsulfonphthalein ($C_{19}H_{14}O_5S$)].

Phenylalanine $C_9H_{11}NO_2$ [Same as the monograph L-Phenylalanine]

Phenylated silica gel for liquid chromatography Prepared for liquid chromatography.

Phenyl benzoate $C_6H_5COOC_6H_5$ White crystals or crystalline powder, having a slight, characteristic odor.

Melting point: 68 - 70°C

Purity Clarity of solution—Dissolve 1.0 g of phenyl benzoate in 20 mL of methanol: the solution is clear.

***o*-Phenylenediamine dihydrochloride** $H_2NC_6H_4NH_2.2HCl$ White to pale yellow or pale red crystals or crystalline powder.

Clarity: a solution (1 in 20) is clear.

Content: not less than 98.0%. Assay—Weigh accurately about 0.15 g of *o*-phenylenediamine dihydrochloride, dissolve in 50 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS (potentiometric titration).

Each mL of 0.1 mol/L sodium hydroxide VS
= 0.009053 g of $H_2NC_6H_4NH_2.2HCl$

Phenylfluorone $C_{19}H_{12}O_5$ [K 9547]

Phenylfluorone-ethanol TS Dissolve 0.050 g of phenylfluorone in 10 mL of a mixture of ethanol (95) and diluted hydrochloric acid (1 in 3), and add thanol (95) to make exactly 500 mL.

Phenylhydrazine $C_6H_5NHNH_2$ [K 8795: 1980, Special class]

Phenylhydrazine hydrochloride See phenylhydrazinium chloride.

Phenylhydrazine hydrochloride TS See phenylhydrazinium chloride TS.

Phenylhydrazinium chloride $C_6H_5NHNH_2.HCl$ [K 8203, Special class]

Phenylhydrazinium chloride TS Dissolve 0.065 g of phenylhydrazinium chloride recrystallized from dilute ethanol, in 100 mL of a solution previously prepared by adding cautiously 170 mL of sulfuric acid to 80 mL of water.

35% Phenyl-methyl silicone polymer for gas chromatography Prepared for gas chromatography.

50% Phenyl-methyl silicone polymer for gas chromatography Prepared for gas chromatography.

65% Phenyl-methyl silicone polymer for gas chromatography Prepared for gas chromatography.

25% Phenyl-25% cyanopropyl-methylsilicone polymer for gas chromatography Prepared for gas chromatography.

1-phenyl-3-methyl-5-pyrazolone See 3-methyl-1-phenyl-5-pyrazolone.

Phloroglucin $C_6H_3(OH)_3.2H_2O$ [K 8846: 1961, Special class]

Phosgene test paper Dissolve 5 g of 4-dimethylaminobenzaldehyde and 5 g of diphenylamine in 100 mL of ethanol (99.5). Immerse a filter paper 5 cm in width in this solution, and allow to dry spontaneously while the paper is suspended in a dark place under clear air. Then cut off the 5-cm portions from the upper side and lower side of the paper, and cut the remaining paper to a length of 7.5 cm.

Preserve in tight, light-resistant containers. Do not use the paper, which has changed to a yellow color.

Phosphate buffer solution for pancreatin Dissolve 3.3 g of anhydrous disodium hydrogenphosphate, 1.4 g of potassium dihydrogenphosphate and 0.33 g of sodium chloride in water to make 100 mL.

0.02 mol/L Phosphate buffer solution, pH 3.0 Dissolve 3.1 g of sodium dihydrogenphosphate dihydrate in 1000 mL of water, and adjust the pH to 3.0 with diluted phosphoric acid (1 in 10).

0.02 mol/L Phosphate buffer solution, pH 3.5 Dissolve 3.1 g of sodium dihydrogenphosphate dihydrate in 1000 mL of water, and adjust the pH to 3.5 with diluted phosphoric acid (1 in 10).

0.1 mol/L Phosphate buffer solution, pH 4.5 Dissolve 13.61 g of potassium dihydrogenphosphate in 750 mL of water, adjust to pH 4.5 with potassium hydroxide TS, and add water to make 1000 mL.

Phosphate buffer solution, pH 6.0 Dissolve 8.63 g of potassium dihydrogenphosphate and 1.37 g of anhydrous disodium hydrogenphosphate in 750 mL of water, adjust the pH to 6.0 with sodium hydroxide TS or diluted phosphoric acid (1 in 15), and add water to make 1000 mL.

0.05 mol/L Phosphate buffer solution, pH 6.0 To 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS for buffer solution add 5.70 mL of 0.2 mol/L sodium hydroxide TS and water to make 200 mL.

Phosphate buffer solution, pH 6.5 Mix 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS for buffer solution and 15.20 mL of 0.2 mol/L sodium hydroxide VS, and add water to make 200 mL.

Phosphate buffer solution, pH 6.8 Dissolve 3.40 g of potassium dihydrogenphosphate and 3.55 g of disodium hydrogenphosphate in water to make 1000 mL.

Phosphate buffer solution, pH 7.0 Mix 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS for buffer solution and 29.54 mL of 0.2 mol/L sodium hydroxide VS, and add water to make 200 mL.

0.05 mol/L Phosphate buffer solution, pH 7.0 Dissolve 4.83 g of dipotassium hydrogenphosphate and 3.02 g of potassium dihydrogenphosphate in 1000 mL of water, and adjust to pH 7.0 with phosphoric acid or potassium hydroxide TS.

0.1 mol/L Phosphate buffer solution, pH 7.0 Dissolve 17.9 g of disodium hydrogenphosphate 12-water in water to make 500 mL (solution A). Dissolve 6.8 g of potassium dihydrogenphosphate in water to make 500 mL (solution B). To a volume of solution A add solution B until the mixture is adjusted to pH 7.0 (about 2:1 by volume of solutions A and B).

Phosphate buffer solution, pH 7.2 Mix 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS for buffer solution and 34.7 mL of 0.2 mol/L sodium hydroxide VS, and add water to make 200 mL.

Phosphate buffer solution, pH 7.4 Mix 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS for buffer solution and 39.50 mL of 0.2 mol/L sodium hydroxide VS, and add water to make 200 mL.

Phosphate buffer solution, pH 8.0 Mix 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS for buffer solution and 46.1 mL of 0.2 mol/L sodium hydroxide VS, and add water to make 200 mL.

0.02 mol/L Phosphate buffer solution, pH 8.0 To 50 mL of 0.2 mol/L potassium dihydrogenphosphate TS add 300 mL of water, adjust the pH to 8.0 with sodium hydroxide TS, and add water to make 500 mL.

0.1 mol/L Phosphate buffer solution, pH 8.0 Dissolve 13.2 g of anhydrous disodium hydrogenphosphate and 0.91 g of potassium dihydrogenphosphate in about 750 mL of water, adjust to pH 8.0 with phosphoric acid, and add water to make 1000 mL.

0.2 mol/L Phosphate buffer solution, pH 10.5 Dissolve 34.8 g of dipotassium hydrogenphosphate in 750 mL of water, adjust to pH 10.5 with 8 mol/L sodium hydroxide

TS, and add water to make 1000 mL.

Phosphate buffer solution, pH 12 To 5.44 g of disodium hydrogenphosphate add 36.5 mL of sodium hydroxide TS and about 40 mL of water, dissolve by shaking well, and add water to make 100 mL.

0.1 mol/L Phosphate buffer solution for ceftibuten, pH 8.0 Dissolve 16.73 g of dipotassium hydrogenphosphate and 0.523 g of potassium dihydrogenphosphate in about 750 mL of water, adjust the pH to 8.0 with phosphoric acid, and add water to make 1000 mL.

Phosphate buffer solution for microplate washing Dissolve 0.62 g of sodium dihydrogenphosphate dihydrate, 9.48 g of disodium hydrogenphosphate 12-water, 52.6 g of sodium chloride, 3.0 g of polysorbate 80 and 1.8 g of polyoxyethylene (40) octylphenyl ether in water to make 600 mL. Dilute this solution 10 times with water before use.

Phosphinic acid H_3PO_2 [K 8440, First class]

Phosphomolybdic acid See phosphomolybdic acid *n*-hydrate.

Phosphomolybdic acid *n*-hydrate $P_2O_5.24MoO_3.nH_2O$ [K 9026: 1991, Special class]

Phosphoric acid H_3PO_4 [K 9005, Special class]

Phosphoric acid-sodium sulfate buffer solution, pH 2.3 Dissolve 28.4 g of anhydrous sodium sulfate in 1000 mL of water, and add 2.7 mL of phosphoric acid. If necessary, adjust to pH 2.3 with 2-aminoethanol.

Phosphoric acid-acetic acid-boric acid buffer solution, pH 2.0 Dissolve 6.77 mL of phosphoric acid, 5.72 mL of acetic acid (100) and 6.18 g of boric acid in water to make 1000 mL. Adjust the pH of this solution to 2.0 with 0.5 mol/L sodium hydroxide VS.

Phosphorus pentoxide See phosphorus (V) oxide.

Phosphorus, red [K 8595: 1961, First class]

Phosphorus (V) oxide P_2O_5 [K 8342, Special class]

Phosphotungstic acid See phosphotungstic acid *n*-hydrate.

Phosphotungstic acid *n*-hydrate $P_2O_5.24WO_3.nH_2O$ [K 9024: 1991, Special class]

Phosphotungstic acid TS Dissolve 1 g of phosphotungstic acid *n*-hydrate in water to make 100 mL.

***o*-Phthalaldehyde** $C_6H_4(CHO)_2$ Greenish yellow powder.

Content: not less than 99%.

Phthalic acid $C_8H_6O_4$ Colorless or white crystalline powder. Soluble in methanol and in ethanol (95), sparingly soluble in water, and practically insoluble in chloroform. Melting point: about 200°C (with decomposition).

Content: not less than 98%. Assay—Weigh accurately about 2.8 g of phthalic acid, add exactly 50 mL of 1 mol/L sodium hydroxide VS and 25 mL of water, and dissolve by heating on a hot plate. After cooling, add 5 drops of phenolphthalein TS, and titrate the excess sodium hydroxide with 0.5 mol/L sulfuric acid VS. Perform a blank determination, and make any necessary correction.

Each mL of 1 mol/L sodium hydroxide VS
= 83.06 mg of $C_8H_6O_4$

Phthalic anhydride $C_8H_4O_3$ [K 8887, Special class]

Phytonadione $C_{31}H_{46}O_2$ [Same as the namesake monograph]

Picric acid See 2,4,6-trinitrophenol.

Picric acid-ethanol TS See 2,4,6-trinitrophenol-ethanol TS.

Picric acid TS See 2,4,6-trinitrophenol TS.

Picric acid TS, alkaline See 2,4,6-trinitrophenol TS, alkaline.

Piperidine hydrochloride $C_5H_{11}N.HCl$ White, crystalline powder. Dissolves in water and in methanol. The pH of the aqueous solution (1 in 20) is between 3.0 and 5.0.

Melting point: 240 - 245°C

Purity Clarity and color of solution—Dissolve 1.0 g of piperidine hydrochloride in 20 mL of water: the solution is clear and colorless.

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

Content: not less than 99.0%. Assay—Dissolve about 0.25 g of piperidine hydrochloride, accurately weighed, in 50 mL of water, add 5 mL of diluted nitric acid (1 in 3), and titrate with 0.1 mol/L silver nitrate VS (potentiometric titration). Perform a blank determination in the same manner.

Each mL of 0.1 mol/L silver nitrate VS
= 12.161 mg of $C_5H_{11}N.HCl$

Polyalkylene glycol monoether for gas chromatography Prepared for gas chromatography.

Polyamide for thin-layer chromatography Prepared for thin-layer chromatography.

Polyamide with fluorescent indicator for thin-layer chromatography Add a fluorescent indicator to polyamide for thin-layer chromatography.

Polyethylene glycol 15000-diepoxide for gas chromatography Prepared for gas chromatography.

Polyethylene glycol 20 M for gas chromatography Prepared for gas chromatography.

Polyethylene glycol 400 for gas chromatography Prepared for gas chromatography.

Polyethylene glycol 6000 for gas chromatography Prepared for gas chromatography.

Polyethylene glycol ester for gas chromatography Prepared for gas chromatography.

Polyoxyethylene hydrogenated castor oil 60 A nonionic surfactant prepared by addition polymerization of ethylene oxide with hydrogenated castor oil. Average molar number of ethylene oxide added is about 60. A white or pale yellow petrolatum-like or waxy substance, having a faint, characteristic odor and a slight, bitter taste. Very soluble in ethyl acetate and in chloroform, freely soluble in ethanol (95), slightly soluble in water, and practically insoluble in diethyl ether.

Identification—(1) To 0.5 g of polyoxyethylene hydrogenated castor oil 60 add 10 mL of water and 5 mL of ammonium thiocyanate-cobalt (II) nitrate TS, and shake thor-

oughly. Add 5 mL of chloroform, shake, and allow to stand: a blue color develops in the chloroform layer.

(2) To 0.2 g of polyoxyethylene hydrogenated castor oil 60 add 0.5 g of potassium bisulfate, and heat: an acrolein-like, irritating odor is perceptible.

(3) To 0.5 g of polyoxyethylene hydrogenated castor oil 60 add 10 mL of water, shake, and add 5 drops of bromine TS: the color of the test solution does not disappear.

Congealing point: 30 - 34°C

pH—To 1.0 g of polyoxyethylene hydrogenated castor oil 60 add 20 mL of water, and dissolve by heating: the pH of the solution is between 3.6 and 6.0.

Acid value: not more than 1.0.

Saponification value: 41 - 51

Hydroxyl value: 39 - 49

Purity (1) Clarity and color of solution—Dissolve 1.0 g of polyoxyethylene hydrogenated castor oil 60 in 20 mL of ethanol: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of polyoxyethylene hydrogenated castor oil 60 according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic—Take 1.0 g of polyoxyethylene hydrogenated castor oil 60, prepare the test solution according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

Water: not more than 2.0% (1 g).

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

Storage: Preserve in tight containers.

Polyoxyethylene (40) octylphenyl ether Obtained by the addition polymerization with ethylene oxide to octylphenol. A colorless or white to pale yellow, liquid, vaseline-like or waxy, having slightly a characteristic odor.

Clarity: a solution (1 in 20) is clear.

Specific gravity d_4^{20}: 1.10 - 1.11

pH: 7.0 - 9.5 (5 w/v%, 25°C).

Polysorbate 20 Chiefly consists of addition polymer of sorbitan monolaurate and ethylene oxide. Pale yellow to yellow liquid, having a faint, characteristic odor.

Identification—(1) To 0.5 g of polysorbate 20 add 10 mL of water and 10 mL of sodium hydroxide TS, boil for 5 minutes, and acidify with dilute hydrochloric acid: an oily fraction is separated.

(2) To 0.5 g of polysorbate 20 add 10 mL of water, shake, and add 5 drops of bromine TS: the red color of the test solution does not disappear.

(3) Saponify 5 g of polysorbate 20 as directed under the Saponification Value, and evaporate ethanol completely. Dissolve the residue in 50 mL of water, acidity with hydrochloric acid (methyl orange), and extract with two 30 mL portions of diethyl ether. Combine the diethyl ether layer, wash with 20 mL portions of water until the washings become neutral, and evaporate the diethyl ether on a water bath: the acid value of the residue is between 275 and 285. Use 50 mL of 0.5 mol/L potassium hydroxide-ethanol VS for saponification.

Acid value: not more than 4.0.

Saponification value: 43 - 55

Loss on drying: not more than 3.0% (5 g, 105°C, 1 hour).

Residue on ignition—Weigh accurately 3 g of polysorbate 20, heat gently at first, and ignite gradually (800 in 1200°C) until the residue is completely incinerated. If any carbonized substance remains, extract with hot water, filter through a sheet of filter paper for quantitative analysis (5C), and ignite the residue with the filter paper. Add the filtrate to it, evaporate to dryness, and ignite carefully until the carbonized substance does not remain. If any carbonized substance still remains, add 15 mL of ethanol (95), crush the carbonized substance with a glass rod, burn the ethanol, and ignite carefully. Cool in a desiccator (silica gel), and weigh the residue accurately: not more than 1.0%.

Polysorbate 80 [Same as the namesake monograph in Part II].

Polyvinyl alcohol $(-CH_2CHOH-)_n$ [K 9550, Special class]

Polyvinyl alcohol I Colorless to white, or pale yellow granules or powder. It is odorless, or has a faint odor of acetic acid. It is tasteless. Practically insoluble in ethanol (95) or in diethyl ether. To polyvinyl alcohol I add water, and heat: A clear, viscous solution is obtained. It is hygroscopic.

Viscosity: 25.0 - 31.0 mm^2/s. Weigh 4.000 g of polyvinyl alcohol I, previously dried, add 95 mL of water, allow to stand for 30 minutes, and heat to dissolve on a water bath under a reflux condenser for 2 hours while stirring. After cooling, add water to make 100.0 g, and mix. Allow to stand still to remove bubbles, and perform the test at 20 ± 0.1°C as directed in Method 1 under the Viscosity Determination.

pH—The pH of a solution of polyvinyl alcohol I (1 in 25) is between 5.0 and 8.0.

Clarity and color of solution—To 1.0 g of polyvinyl alcohol I add 20 mL of water, disperse by well stirring, warm between 60°C and 80°C for 2 hours, and cool: the solution is colorless and clear.

Saponification value: 98.0 - 99.0 mol%. Weigh accurately about 3.0 g of polyvinyl alcohol I, previously dried, transfer to a glass-stoppered, conical flask, add 100 mL of water, and dissolve by heating on a water bath. After cooling, add exactly 25 mL of 0.1 mol/L sodium hydroxide VS, stopper tightly, and allow to stand for 2 hours. Then add exactly 30 mL of 0.05 mol/L sulfuric acid VS, shake well, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination in the same manner, and make any necessary correction. However, when the volume of 0.1 mol/L sodium hydroxide VS consumed in the test is 25 mL or more, use about 2.0 g of the sample.

$$\text{Saponification value (mol\%)} = 100 - \frac{44.05A}{60.05 - 0.42A}$$

$$A = \frac{0.6005 \times (a - b)f}{\text{amount (g) of the sample}}$$

a: Volume (mL) of 0.1 mol/L sodium hydroxide VS consumed in the test

b: Volume (mL) of 0.1 mol/L sodium hydroxide VS consumed in the blank test

f: Molarity factor of 0.1 mol/L sodium hydroxide VS

Polyvinyl alcohol II Colorless to white or pale yellow granules or powder. It is odorless, or has a faint odor of acetic acid. It is tasteless. Practically insoluble in ethanol