Anhydrous sodium sulfate See sodium sulfate, anhydrous.

Anhydrous sodium sulfite See sodium sulfite, anhydrous.

Aniline $C_6H_5NH_2$ [K 8042, Special class]

Animal tissue peptone See peptone, animal tissue.

***p*-Anisaldehyde** See 4-methoxybenzaldehyde.

***p*-Anisaldehyde-acetic acid TS** See 4-methoxyhenzaldehyde-acetic acid TS.

***p*-Anisaldehyde-sulfuric acid TS** See 4-methoxybenzaldehyde-sulfuric acid TS.

Anisole C_7H_8O [K 8041, Special class]

Anthrone $C_{14}H_{10}O$ [K 8082, Special class]

Anthrone TS Dissolve 35 mg of anthrone in 100 mL of sulfuric acid.

Anti-A type antibody for blood typing Conforms to the requirements of antibody for blood typing.

Anti-B type antibody for blood typing Conforms to the requirements of antibody for blood typing.

Anti-bradykinin antibody A colorless to light brown, clear solution prepared by dissolving rabbit origin anti-bradykinin antibody in 0.04 mol/L phosphate buffer solution, pH 7.0 containing 1 mg/mL of bovine serum albumin.

Performance test—To a suitable amount of anti-bradykinin antibody to be tested add 0.04 mol/L phosphate buffer solution, pH 7.0 containing 1 mg/mL bovine serum albumin to make a 1 vol% solution. Perform the test with 0.1 mL of this solution as directed in the Purity (2) under Kallidinogenase, and determine the absorbances at 490 - 492 nm, A_1 and A_2, of the standard solution (1) and the standard solution (7): the value, $A_2 - A_1$, is not less than 1.

Anti-bradykinin antibody TS To 0.15 mL of anti-bradykinin antibody, 15 mg of bovine serum albumin, 2.97 mg of sodium dihydrogenphosphate dihydrate, 13.5 mg of disodium hydrogenphosphate 12-water and 13.5 mg of sodium chloride add water to make 15 mL, and lyophilize. Dissolve this in 15 mL of water. Prepare before use.

Antimony (III) chloride $SbCl_3$ [K 8400, Special class]

Antimony (III) chloride TS Wash chloroform with an equal volume of water twice or three times, add freshly ignited and cooled potassium carbonate, and allow to stand overnight in a well-closed container protected from light. Separate the chloroform layer, and distil it, preferably with protection from light. With this chloroform, wash the surface of antimony (III) chloride until the rinsing solution becomes clear, add the chloroform to this antimony (III) chloride to make a saturated solution, and place in light-resistant, glass-stoppered bottles. Prepare before use.

Antimony trichlorid See antimony (III) chloride.

Antimony trichlorid TS See Antimony (III) chlorid TS.

Antipyrine $C_{11}H_{12}N_2O$ [Same as the namesake monograph]

Anti-rabbit antibody-coated wells Wells of a polystyrene microplate coated with goat origin anti-rabbit IgG antibody.

Anti-ulinastatin rabbit serum To a suitable amount of Ulinastatin having the specific activity of more than 3000 Units per mg protein add isotonic sodium chloride solution so that each mL of the solution contains about 1 mg of protein. To 1 mL of this solution add 1 mL of complete Freund's adjuvant, and emulsify completely. Intracutaneously, inject the emulsion so obtained into a rabbit weighing about 2 kg. Repeat the injection at least 4 times at one-week intervals, and draw the blood of the animal from the carotid artery after the antibody titer reaches 16 times or more. Separate the serum after the blood has coagulated. Preserve at below −20°C.

Anti-urokinase serum Take Urokinase containing not less than 140,000 Unit per mg of protein, dissolve in isotonic sodium chloride solution to make a solution containing 1 mg of protein per mL, and emulsify with an equal volume of Freund's complete adjuvant. Inject intracutaneously three 2-mL portions of the emulsion to a healthy rabbit weighed between 2.5 kg and 3.0 kg in a week interval. Collect the blood from the rabbit at 7 to 10 days after the last injection, and prepare the anti-serum.

Performance test—Dissolve 1.0 g of agar in 100 mL of boric acid-sodium hydroxide buffer solution, pH 8.4, by warming, and pour the solution into a Petri dish to make a depth of about 2 mm. After cooling, bore three of a pair-well 2.5 mm in diameter with a space of 6 mm each other. In one of the wells of each pair-well, place 10 μL of anti-urokinase serum, and in each another well, place 10 μL of a solution of Urokinase containing 30,000 Units per mL in isotonic sodium chloride solution, 10 μL of human serum and 10 μL of human urine, respectively, and allow to stand for overnight: a precipitin line appears between anti-urokinase serum and urokinase, and not appears between anti-urokinase serum and human serum or human urine.

Aprotinin A clear and colorless liquid containing aprotinin extracted from the lung or parotid gland of a healthy cattle. The pH is between 5.0 and 7.0.

Content: not less than 15,000 KIE Units and not more than 25,000 KIE Units of aprotinin per mL. Assay—(i) Trypsin solution: Weigh an amount of crystallized trypsin equivalent to about 250 FIP Units of trypsin according to the labeled FIP Units, and dissolve in 0.001 mol/L hydrochloric acid TS to make exactly 10 mL. Prepare before use, and preserve in ice. (ii) Sample solution: Dilute a suitable quantity of aprotinin with sodium tetraborate-calcium chloride buffer solution, pH 8.0 so that each mL of the solution contains 800 KIE Units of aprotinin, and use this solution as the sample solution. (iii) Apparatus: Use a glass bottle as a reaction reservoir, 20 mm in inside diameter and 50 mm in height, equipped with a rubber stopper for attachment to a glass/silver-silver chloride electrode, a nitrogen-induction tube and an exhaust port. Fix the reaction reservoir in a thermostat, and keep the temperature of the bath at 25 ± 0.1°C by means of a precise thermoregulator. (iv) Procedure: To 5.0 mL of *N*-α-benzoyl-L-arginine ethyl ester TS add 45.0 mL of sodium tetraborate-calcium chloride buffer solution, pH 8.0, and use this solution as the substrate solution. Pipet 1 mL of the trypsin solution, add sodium tetraborate-calcium chloride buffer solution, pH 8.0 to make exactly 10 mL, and use this solution as the test solution I. Transfer 10.0 mL of the substrate solution to the reac-

tion reservoir, adjust the pH of the solution to 8.00 by adding dropwise 0.1 mol/L sodium hydroxide VS while stirring and passing a current of nitrogen, add exactly 1 mL of the test solution I previously allowed to stand at 25 ± 0.1°C for 10 minutes, then immediately add dropwise 0.1 mol/L sodium hydroxide VS by a 50-μL micropipet (minimum graduation of 1 μL), while stirring, to keep the reaction solution at pH 8.00, and read the amount of 0.1 mol/L sodium hydroxide VS consumed and the reaction time when the pH reached 8.00. Continue this procedure up to 6 minutes. Separately, pipet 2 mL of the trypsin solution and 1 mL of the sample solution, add sodium tetraborate-calcium chloride buffer solution, pH 8.0 to make exactly 10 mL, and use this solution as the test solution II. Transfer 10.0 mL of the substrate solution to the reaction reservoir, adjust the pH of the solution to 8.00, while stirring and passing a current of nitrogen, add exactly 1 mL of the test solution II, previously allowed to stand at 25 ± 0.1°C for 10 minutes, and proceed in the same manner. Separately, transfer 10.0 mL of the substrate solution to the reaction reservoir, adjust the pH of the solution to 8.00, while stirring and passing a current of nitrogen, add 1 mL of sodium tetraborate-calcium chloride buffer solution, pH 8.0, previously allowed to stand at 25 ± 0.1°C for 10 minutes, and perform a blank determination in the same manner. (v) Calculation: Plot the amount of consumption (μL) of 0.1 mol/L sodium hydroxide VS against the reaction time (minutes), select linear reaction times, t_1 and t_2, designate the corresponding consumption amount of 0.1 mol/L sodium hydroxide VS as v_1 and v_2, respectively, and designate μmol of sodium hydroxide consumed per minute as M.

$$M\ (\mu\text{mol NaOH/min}) = \frac{v_2 - v_1}{t_2 - t_1} \times \frac{1}{10} \times f$$

f: Factor of 0.1 mol/L sodium hydroxide VS

$$\text{KIE Units per mL of aprotinin to be tested} = \frac{2(M_A - M_0) - (M_B - M_0)}{L} \times n \times 32.5$$

L: Amount (mL) of the sample solution added to the test solution II
n: Dilution coefficient of aprotinin to be tested
M_A: μmol of sodium hydroxide consumed in 1 minute when the test solution I is used
M_B: μmol of sodium hydroxide consumed in 1 minute when the test solution II is used
M_0: μmol of sodium hydroxide consumed in 1 minute when the solution for blank determination is used
32.5: Equivalent coefficient for calculation of KIE Units from FIP Units

One KIE Unit means an amount of aprotinin making a reduction of 50% off the potency of 2 Units of kallidinogenase at pH 8.0 and room temperature for 2 hours.

Storage—Preserve in a light-resistant, hermetic container and in a cold place.

Aprotinin TS Measure an appropriate amount of aprotinin, and dissolve in 0.05 mol/L phosphate buffer solution, pH 7.0 to prepare a solution containing 50 KIE Units per mL.

Aqua regia Add 1 volume of nitric acid to 3 volumes of hydrochloric acid. Prepare before use.

Arbutin for component determination Use arbutin for thin-layer chromatography meeting the following additional specifications.

Absorbance $E^{1\%}_{1\,\text{cm}}$ (280 nm): 70 – 76 [4 mg, previously dried in a desiccator (in vaccum, silica gel), 12 hours, water, 100 mL].

Purity Related substances—Dissolve 0.04 g of arbutin for component determination in 100 mL of water, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water 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 the both solutions by the automatic integration method: the total area of the peaks other than that of arbutin from the sample solution is not larger than the peak area of arbutin from the standard solution (1).

Operating conditions

Proceed the operating conditions in the Component determination under Bearberry Leaf except detection sensitivity and time span of measurement.

Detection sensitivity: Pipet 1 mL of the standard solution (1), add water to make exactly 20 mL, and use this solution as the standard solution (2). Adjust the detection sensitivity so that the peak area of arbutin obtained from 10 μL of the standard solution (2) can be measured by the automatic integration method and the peak height of arbutin 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 arbutin after the solvent peak.

Arbutin for thin-layer chromatography $C_{12}H_{16}O_7.nH_2O$ Colorless to white crystals or crystalline powder, and odorless. Freely soluble in water, soluble in methanol, sparingly soluble in ethanol (95), and practically insoluble in ethyl acetate and in chloroform.

Melting point: 199 – 201°C

Purity Related substances—Dissolve 1.0 mg of arbutin for thin-layer chromatography in exactly 1 mL of a mixture of ethanol (95) and water (7:3). Perform the test with 20 μL of this solution as directed in the Identification (2) under Bearberry Leaf: any spot other than the main spot at the *Rf* value of about 0.4 does not appear.

Arecoline hydrobromide for thin-layer chromatography $C_8H_{13}BrNO_3.HBr$ White crystals. Freely soluble in water, soluble in methanol, and practically insoluble in diethyl ether.

Melting point: 169 – 171°C

Purity Related substances—Dissolve 0.050 g of arecoline hydrobromide for thin-layer chromatography in exactly 10 mL of methanol. Perform the test with 10 μL of this solution as directed in the Identification under Areca: any spot other than the principal spot at the *Rf* value of about 0.4 does not appear.

L-Arginine $C_6H_{14}N_4O_2$ White, crystals or crystalline powder. It has a characteristic odor.

Optical rotation $[\alpha]^{20}_D$: +26.9 – +27.9° (After drying, 4 g, 6 mol/L hydrochloric acid TS, 50 mL, 200 mm).

Loss on drying: not more than 0.50% (1 g, 105°C, 3 hours).

Content: not less than 98.0% and not more than 102.0%. Assay—Weigh accurately about 0.15 g of L-arginine, previously dried, dissolve in 3 mL of formic acid, add 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes to green through yellow (indicator: 10 drops of *p*-naphtholbenzein TS). Perform a blank determination in the same manner and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid
= 8.710 mg of $C_6H_{14}N_4O_2$

L-Arginine hydrochloride $C_6H_{14}N_4O_2.HCl$ [Same as the namesake monograph]

Arsenazo III $C_{22}H_{18}As_2N_4O_{14}S_2$ [K 9524]

Arsenazo III TS Dissolve 0.1 g of arsenazo III in water to make 50 mL.

Arsenic-free zinc See zinc for arsenic analysis.

Arsenic (III) trioxide As_2O_3 [K 8044, Arsenic (III) trioxide, Special class]

Arsenic (III) trioxide (standard reagent) [K 8005, Diarsenic trioxide, Standard reagent for volumetric analysis]

Arsenic (III) trioxide TS Add 1 g of arsenic (III) trioxide to 30 mL of a solution of sodium hydroxide (1 in 40), dissolve by heating, cool, and add gently acetic acid (100) to make 100 mL.

Arsenic trioxide See arsenic (III) trioxide.

Arsenic trioxide TS See arsenic (III) trioxide TS.

Arsenic trioxid (standard reagent) See Arsenic (III) trioxide (standard reagent).

Ascorbic acid See L-ascorbic acid.

L-Ascorbic acid $C_6H_8O_6$ [K 9502, L(+)-Ascorbic Acid, Special class]

Ascorbic acid for iron limit test See L-ascorbic acid.

0.02 g/dL L-Ascorbic acid-hydrochloric acid TS Dissolve 0.025 g of L-ascorbic acid in 25 mL of methanol, add carefully 100 mL of hydrochloric acid, and mix. Prepare before use.

0.05 g/dL L-Ascorbic acid-hydrochloric acid TS Dissolve 0.05 g of L-ascorbic acid in 30 mL of methanol, add carefully hydrochloric acid to make 100 mL. Prepare before use.

0.012 g/dL L-Ascorbic acid-hydrochloric aicd TS Dissolve 0.015 g of L-ascorbic acid in 25 mL of methanol, add carefully 100 mL of hydrochloric acid, and mix. Prepare before use.

L-Aspartic acid $C_4H_7O_4N$ [K 9045, Special class]

Aspartic acid See L-aspartic acid.

Aspirin $C_9H_8O_4$ [Same as the namesake monograph]

Atropine sulfate for assay [Same as the monograph Atropine Sulfate. When dried, it contains not less than 99.0% of atropine sulfate [$(C_{17}H_{23}NO_3)_2.H_2SO_4$]].

Atropine sulfate for thin-layer chromatography Use atropine sulfate for assay meeting the following additional specifications. Weigh accurately about 0.050 g of atropine sulfate for assay, dissolve in ethanol (95) to make exactly 10 mL, and use this solution as the sample solution. Perform the test with the sample solution as directed under the Thin-layer Chromatography. Spot 50 μL of the solution on a plate of silica gel for thin-layer chromatography, develop the plate with a mixture of chloroform and diethylamine (9:1) to a distance of about 10 cm, air-dry the plate, and spray evenly chloroplatinic acid-potassium iodide TS on the plate: any spot other than the spot at the *Rf* value of about 0.4 does not appear.

A-type erythrocyte suspension Prepare a suspension containing 1 vol% of erythrocyte separated from human A-type blood in isotonic sodium chloride solution.

Baicalin for thin-layer chromatography $C_{21}H_{18}O_{11}.H_2O$ Light yellow odorless powder. Slightly soluble in methanol, and practically insoluble in water and in diethyl ether.
Melting point: about 206°C (with decomposition).
Purity Related substance—Dissolve 1.0 mg of baicalin for thin-layer chromatography in exactly 1 mL of methanol. Perform the test with 10 μL of this solution as directed in the Identification (2) under Scutellaria Root: any spot other than the principal spot at the *Rf* value of about 0.4 does not appear.

Balsam Canada balsam for microscopy. Before use, dilute to a suitable concentration with xylene.

Bamethan sulfate $(C_{12}H_{19}NO_2)_2.H_2SO_4$ [Same as the namesake monograph]

Barbaloin for thin-layer chromatography $C_{21}H_{22}O_9$ Light yellow, crystalline powder. Freely soluble in methanol, practically insoluble in water and in diethyl ether.
Melting point: 148°C
Purity Related substances—Dissolve 1.0 mg of barbaloin 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 Aloe: any spot other than the principal spot at the *Rf* value of about 0.6 does not appear.

Barbital $C_8H_{12}N_2O_3$ [Same as the namesake monograph]

Barbital buffer solution Dissolve 15 g of barbital sodium in 700 mL of water, adjust the pH to 7.6 with dilute hydrochloric acid, and filter.

Barbital sodium $C_8H_{11}N_2NaO_3$ White, odorless crystals of crystalline powder, having a bitter taste. Freely soluble in water, slightly soluble in ethanol (95), and practically insoluble in diethyl ether.
pH—The pH of a solution of barbital sodium (1 in 200) is between 9.9 and 10.3.
Loss on drying: not more than 1.0% (1 g, 105°C, 4 hours).
Content: not less than 98.5%. Assay—Weigh accurately about 0.5 g of barbital sodium, previously dried, transfer to a separator, dissolve in 20 mL of water, add 5 mL of ethanol (95) and 10 mL of dilute hydrochloric acid, and extract with 50 mL of chloroform. Then extract with three 25-mL portions of chloroform, combine the total extract, wash with two 5-mL portions of water, and extract the washings with two 10-mL portions of chloroform. Combine the chlo-

roform extracts, and filter into a conical flask. Wash the filter paper with three 5-mL portions of chloroform, combine the filtrate and the washings, add 10 mL of ethanol (95), and titrate with 0.1 mol/L potassium hydroxide-ethanol VS until the color of the solution changes from yellow to purple through light purple (indicator: 2 mL of alizarin yellow GG-thymolphthalein TS). Perform a blank determination in the same manner.

Each mL of 0.1 mol/L potassium hydroxide-ethanol VS
= 20.618 mg of $C_8H_{11}N_2NaO_3$

Barium chloride See barium chloride dihydrate.

Barium chloride dihydrate $BaCl_2.2H_2O$ [K 8155, Special class]

Barium chloride TS Dissolve 12 g of barium chloride dihydrate in water to make 100 mL (0.5 mol/L).

Barium hydroxide See barium hydroxide octahydrate.

Barium hydroxide octahydrate $Ba(OH)_2.8H_2O$ [K 8577, Special class] Store in tightly stoppered containers.

Barium hydroxide TS Saturate barium hydroxide octahydrate in freshly boiled and cooled water (0.25 mol/L). Prepare before use.

Barium nitrate $Ba(NO_3)_2$ [K 8565, Special class]

Barium nitrate TS Dissolve 6.5 g of barium nitrate in water to make 100 mL (0.25 mol/L).

Barium oxide BaO [K 8428: 1961, For drying]

Barium perchlorate $Ba(ClO_4)_2$ [K 9551, Special class]

Bencyclane Fumarate for assay $C_{19}H_{31}NO.C_4H_4O_4$ [Same as the monograph Bencyclane Fumarate. When dried, it contains not less than 99.0% of $C_{19}H_{31}NO.C_4H_4O_4$. Proceed as directed in the Identification (5) under Bencylane Fumarate Tablets: any spot other than the principal spot does not appear.]

Benzaldehyde C_6H_5CHO [K 8857, First class]

Benzalkonium chloride [Same as the namesake monograph]

Benzene C_6H_6 [K 8858, Special class]

Benzethonium chloride for assay $C_{27}H_{42}ClNO_2$ [Same as the monograph Benzethonium Chloride. When dried, it contains not less than 99.0% of benzethonium chloride ($C_{27}H_{42}ClNO_2$).]

Benzoic acid C_6H_5COOH [K 8073, Special class]

Benzophenone $C_6H_5COC_6H_5$ [K 8861: 1961, Special class]

***p*-Benzoquinone** $C_6H_4O_2$ Yellow to yellow-brown, crystals or crystalline powder, having a pungent odor. Soluble in ethanol (95) and in diethyl ether, slightly soluble in water. It is gradually changed to a blackish brown color by light.

Melting point: 111 – 116°C

Content: not less than 98.0%. Assay—Weigh accurately about 0.1 g of *p*-benzoquinone, place in an iodine bottle, add exactly 25 mL of water and 25 mL of diluted sulfuric acid (1 in 15), dissolve 3 g of potassium iodide by shaking, and titrate with 0.1 mol/L sodium thiosulfate VS (indicator: 3 mL of starch TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium thiosulfate VS
= 5.405 mg of $C_6H_4O_2$

***p*-Benzoquinone TS** Dissolve 1 g of *p*-benzoquinone in 5 mL of acetic acid (100), and add ethanol (95) to make 100 mL.

***N*-α-Benzoyl-L-arginine-4-nitroanilide hydrochloride** $C_{19}H_{22}N_6O_4.HCl$ Light yellow crystalline powder.

Optical rotation $[\alpha]_D^{20}$: +45.5 – +48.0° (after drying, 0.5 g, *N,N*-dimethylformamide, 25 mL, 100 mm).

Purity Related substances—Dissolve 0.20 g of *N*-α-benzoyl-L-arginine-4-nitroanilide hydrochloride in 10 mL of *N,N*-dimethylformamide, and use this solution as the sample solution. Perform the test with this solution as directed under the Thin-layer Chromatography. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography, develop the plate with a mixture of 1-butanol, water and acetic acid (100) (4:1:1) to a distance of about 10 cm, and air-dry the plate. Exposure the plate to a vapor of iodine: only one spot appears.

***N*-α-Benzoyl-L-arginine-4-nitroanilide TS** Dissolve 0.1 g of *N*-α-benzoyl-L-arginine-4-nitroanilide hydrochloride in water to make 100 mL.

***N*-α-Benzoyl-L-arginine ethyl ester hydrochloride** $C_{15}H_{22}N_4O_3.HCl$ White crystals or crystalline powder. Freely soluble in water and in ethanol (95), and slightly soluble in diethyl ether.

Melting point: 129 – 133°C

Optical rotation $[\alpha]_D^{20}$: −15.5 – −17.0° (2.5 g, water, 50 mL, 100 mm).

Purity (1) Clarity and color of solution—Dissolve 0.1 g of *N*-α-benzoyl-L-arginine ethyl ester hydrochloride in 20 mL of water: the solution is clear and colorless.

(2) Other amino acids—Weigh 0.1 g of *N*-α-benzoyl-L-arginine ethyl ester hydrochloride, dissolve in 6 mL of water, add 4 mL of hydrochloric acid, heat in a boiling water bath for 5 minutes to decompose, and use this solution as the sample solution. Perform the test with the sample solution as directed under the Paper Chromatography. Spot 5 μL of the sample solution on a chromatographic filter paper. Develop with a mixture of water, acetic acid (100) and 1-butanol (5:4:1) to a distance of about 30 cm, and air-dry the paper. Spray evenly a solution of ninhydrin in acetone (1 in 50) upon the paper, and heat at 90°C for 10 minutes: only one purple spot appears.

Content: not less than 99.0%. Assay—Weigh accurately about 0.6 g of *N*-α-benzoyl-L-arginine ethyl ester hydrochloride, dissolve in 50 mL of water, neutralize with 0.1 mol/L sodium hydroxide VS, if necessary, and titrate with 0.1 mol/L silver nitrate VS (indicator: 4 drops of dichlorofluorescein TS).

Each mL of 0.1 mol/L silver nitrate VS
= 34.283 mg of $C_{15}H_{22}N_4O_3.HCl$

***N*-α-Benzoyl-L-arginine ethyl ester TS** Dissolve 0.07 g of *N*-α-benzoyl-L-arginine ethyl ester hydrochloride in freshly boiled and cooled water to make exactly 10 mL.

Benzoyl chloride C_6H_5COCl [K 8158, Special class]

Benzoyl peroxide, 25% water containing $(C_6H_5CO)_2O_2$ White moist crystals or powder. Soluble in diethyl ether and