117

99.0% of ajmaline $(C_{20}H_{26}N_2O_2)$.]

L-Alanine C₃H₇NO₂ [K 9101, Special class]

Albumin TS Carefully separate the white from the yolk of a fresh hen's egg. Shake the white with 100 mL of water until the mixture is thoroughly mixed, and filter. Prepare before use.

Aldehyde dehydrogenase Each mg contains not less than 2 enzyme activity units. White powder.

Assay-Dissolve about 0.02 g of aldehyde dehydrogenase, accurately weighed, in 1 mL of water, add ice-cold solution of bovine serum albumin (1 in 100) to make exactly 200 mL, and use this solution as the sample solution. In a spectrophotometric cell, place 2.50 mL of pyrophosphate buffer solution, pH 9.0, 0.20 mL of a solution prepared by dissolving 0.0200 g of β -nicotinamide adenine dinucleotide (NAD) to make exactly 1 mL, 0.10 mL of a pyrazole solution (17 in 2500) and 0.10 mL of the sample solution, stir, stopper tightly, and allow to stand at 25 ± 1 °C for 2 minutes. To this solution add 0.01 mL of an acetaldehyde solution (3 in 1000), stir, stopper tightly, determine every 30 seconds the absorbance at 340 nm as directed under the Ultraviolet-visible Spectrophotometry, and calculate a change (ΔA) in absorbance per minute starting from the spot where the relation of time and absorbance is shown with a straight line. One enzyme activity unit means an amount of enzyme which oxidizes 1 µmol of acetaldehyde per minute when the test is conducted under the conditions of the Procedure.

Enzyme activity unit (unit/mg) of aldehyde dehydrogenase

$$=\frac{2.91\times\Delta A\times200}{6.3\times W\times0.10\times1000}$$

W: Amount of sample taken (g)

Aldehyde dehydrogenase TS Dissolve an amount equivalent to 70 aldehyde dehydrogenase units in 10 mL of water. Prepare before use.

Aldehyde-free ethanol See ethanol, aldehyde-free.

Alizarin complexone $C_{19}H_{15}NO_8$ (1,2-Dihydroxyanthraquino-3-ylmethylamine-N,N-diacetate) A yellow-brown powder. Soluble in ammonia TS, and practically insoluble in water, in ethanol (95) and in diethl ether.

Sensitivity—Dissolve 0.1 g of alizarin complexone by adding 2 drops of ammonia solution (28), 2 drops of ammonium acetate TS and 20 mL of water. To 10 mL of this solution add acetic acid-potassium acetate buffer solution, pH 4.3, to make 100 mL. Place 1 drop of this solution on a white spot plate, add 1 drop of a solution of sodium fluoride (1 in 100,000) and 1 drop of cerium (III) nitrate hexahydrate TS, stir, and observe under scattered light after 1 minute: a blue-purple color is produced, and the color of the control solution is red-purple. Use a solution prepared in the same manner, to which 1 drop of water is added in place of a solution of sodium fluoride, as the control solution.

Alizarin complexone TS Dissolve 0.390 g of alizarin complexone in 20 mL of a freshly prepared solution of sodium hydroxide (1 in 50), then add 800 mL of water and 0.2 g of sodium acetate trihydrate, and dissolve. Adjust the pH to 4 to 5 with 1 mol/L hydrochloric acid VS, and add water to make 1000 mL.

Alizarin red S C₁₄H₇NaO₇S.H₂O [K 8057, Special class]

Alizarin red S TS Dissolve 0.1 g of alizarin red S in water to make 100 mL, and filter if necessary.

Alizarin S See alizarin red S.

Alizarin S TS See alizarin red S TS.

Alizarin yellow GG $C_{13}H_8N_3NaO_5$ [K 8056, Special class]

Alizarin yellow GG-thymolphthalein TS Mix 10 mL of alizarin GG TS with 20 mL of thymolphthalein TS.

Alizarin yellow GG TS Dissolve 0.1 g of alizarin yellow GG in 100 mL of ethanol (95), and filter if necessary.

Alkaline blue tetrazolium TS See blue tetrazolium TS, alkaline

Alkaline copper TS Dissolve 70.6 g of disodium hydrogen-phosphate 12-water, 40.0 g of potassium sodium tartrate tetrahydrate and 180.0 g of anhydrous sodium sulfate in 600 mL of water, and add 20 mL of a solution of sodium hydroxide (1 in 5). To this mixture add, with stirring, 100 mL of a solution of copper (II) sulfate (2 in 25), 33.3 mL of 0.05 mol/L potassium iodate VS and water to make 1000 mL.

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

Alkaline hydroxylamine TS See hydroxylamine TS, alkaline.

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

Alkaline picric acid TS See 2,4,6-trinitrophenol TS, alkaline.

Alkaline potassium ferricyanide TS See potassium hexacyanoferrate (III) TS, alkaline.

Alkylene glycol phthalate ester for gas chromatography Prepared for gas chromatography.

 α -Alumina for specific surface area determination α -Al₂O₃ Prepared for specific surface area determination.

 α -Alumina for thermal analysis α -Al₂O₃ Prepared for thermal analysis.

Aluminon C₂₂H₂₃N₃O₉ [K 8011, Special class.]

Aluminon TS Dissolve 0.1 g of aluminon in water to make 100 mL, and allow this solution to stand for 24 hours.

Aluminum Al [K 8069, Special class].

Aluminum chloride See aluminum (III) chloride hexahydrate.

Aluminum chloride TS Dissolve 64.7 g of aluminum (III) chloride hexahydrate in 71 mL of water, add 0.5 g of activated charcoal, then shake for 10 minutes, and filter. Adjust the pH of the filtrate to 1.5 with a solution of sodium hydroxide (1 in 100) with stirring, and filter if necessary.

Aluminum (III) chloride hexahydrate AlCl₃.6H₂O [K 8114, Special class]

Aluminum oxide Al₂O₃ White crystals, crystalline

powder, or powder. Boiling point: about 3000°C. Melting point: about 2000°C.

Aluminum potassium sulfate 12-water AlK(SO₄)₂.-12H₂O [K 8255, Special class]

Amidosulfuric acid (standard reagent) HOSO₂NH₂ [K 8005, Standard substance for volumetric analysis]

Amidotrizoic acid for assay $C_{11}H_9I_3N_2O_4$ [Same as the monograph Amidotrizoic Acid] It contains not less than 99.0% of $C_{11}H_9I_3N_2O_4$, calculated on the dried basis.

Aminoacetic acid See glycine.

p-Aminoacetophenone See 4-aminoacetophenone.

p-Aminoacetophenone TS See 4-aminoacetophenone TS.

- **4-Aminoacetophenone** H₂NC₆H₄COCH₃ [K 8047: 1978, *p*-Aminoacetophenone, Special class]
- **4-Aminoacetophenone TS** Dissolve 0.100 g of 4-aminoacetophenone in methanol to make exactly 100 mL.
- **4-Aminoantipyrine** $C_{11}H_{13}N_3O$ [K 8048, Special class]
- **4-Aminoantipyrine hydrochloride** $C_{11}H_{13}N_3O.HCl$ Light yellow crystalline powder. It dissolves in water. Melting point: $232 238^{\circ}C$ (decomposition).

Purity Clarity of solution—Dissolve 1 g of 4-amino-antipyrine hydrochloride in 25 mL of water: the solution is almost clear.

Content: 100.6 - 108.5%. Assay—Weigh accurately about 0.5 g of 4-aminoantipyrine hydrochloride, dissolve in 50 mL of water, and, if necessary, neutralize with 0.1 mol/L sodium hydroxide VS (indicator: red litmus paper). Add 4 drops of dichlorofluorescein TS, and titrate with 0.1 mol/L silver nitrate VS.

Each mL of 0.1 mol/L silver nitrate VS = 23.970 mg of $C_{11}H_{13}N_3O.HCl$

- **4-Aminoantipyrine hydrochloride TS** Dissolve 1 g of 4-aminoantipyrine hydrochloride in water to make 50 mL.
- **4-Aminoantipyrine TS** Dissolve 0.1 g of 4-aminoantipyrine in 30 mL of water, add 10 mL of a solution of sodium carbonate decahydrate (1 in 5), 2 mL of sodium hydroxide TS and water to make 100 mL. Prepare before use.
 - p-Aminobenzoic acid See 4-aminobenzoic acid.
- **4-Aminobenzoic acid** $C_7H_7NO_2$ White to very pale yellow crystalline powder. A solution of *p*-aminobenzoic acid in ethanol (95) (1 in 100) is clear.
- **2-Amino-1-butanol** CH₃CH₂CH(NH₂)CH₂OH Clear, colorless to light yellow liquid. Miscible with water and dissolves in methanol.

Refractive index n_D^{20} : 1.450 – 1.455

Specific gravity d_{20}^{20} : 0.944 - 0.950

Purity Related substances—Dissolve 0.050 g of 2-amino-1-butanol in 10 mL of methanol, measured exactly, and perform the test with 12 μ L of this solution as directed in the Purity (4) under Ethambutol Hydrochloride: any spot other than the principal spot at the Rf value of about 0.3 does not appear.

2-Amino-5-chlorobenzophenone for thin-layer chromatography $C_{13}H_{10}ClNO$ Yellow, crystalline powder.

Melting point: 97 - 101°C

Purity Related substances—Dissolve 0.010 g of 2-amino-5-chlorobenzophenone for thin-layer chromatography in methanol to make exactly 200 mL, and perform the test with this solution as directed in the purity (3) under Chlordiazepoxide: any spot other than the principal spot at the Rf value about 0.7 does not appear.

2-Aminoethanol NH₂CH₂CH₂OH [K 8109, Special class]

N-Aminohexamethyleneimine (CH₂)₆NNH₂ Clear, colorless to pale yellow liquid.

Refraction index n_D^{20} : 1.482 – 1.487 Specific gravity d_{20}^{20} : 0.936 – 0.942

- **4-Amino-***N*,*N***-diethylaniline sulfate TS** Dissolve 0.2 g of 4-amino-*N*,*N*-diethylaniline in water to make 100 mL. Prepare before use, protected from light.
- **4-Amino-**N,N-diethylaniline sulfate $H_2NC_6H_4N(C_2H_5)_2$. $H_2SO_4.H_2O$ White to slightly colored powder. It dissolves in water.

Melting point: 173 - 176°C

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

- **2-Amino-2-hydroxymethyl-1,3-propanediol** C₄H₁₁NO₃ [K 9704, Special class]
- 1-Amino-2-naphthol-4-sulfonic acid $C_{10}H_9NO_4S$ [K 8050, Special class]
- 1-Amino-2-naphthol-4-sulfonic acid TS Mix thoroughly 5 g of anhydrous sodium sulfite, 94.3 g of sodium bisulfite and 0.7 g of 1-amino-2-naphthol-4-sulfonic acid. Before use, dissolve 1.5 g of this mixture in water to make 10 mL.
 - m-Aminophenol See 3-aminophenol.
 - 3-Aminophenol H₂NC₆H₄OH [K 8052: 1964, First class]
- **p-Aminophenol hydrochloride** See 4-aminophenol hydrochloride.
- **4-Aminophenol hydrochloride** $HOC_6H_4NH_2.HCl$ White to pale colored crystals. Freely soluble in water and in ethanol (95). Melting point: about $306^{\circ}C$ (with decomposition).

Content: not less than 99.0%. Assay—Weigh accurately about 0.17 g of 4-aminophenol hydrochloride, dissolve in 50 mL of acetic acid for nonaqueous titration and 5 mL of mercury (II) acetate TS for nonaqueous titration, and titrate with 0.1 mol/L perchloric acid-1,4-dioxane VS (indicator: 1 mL of α -naphtholbenzeine TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid-1,4-dioxane VS = 14.559 mg of C_6H_8NOCl

Storage—Preserve in tight, light-resistant containers.

Aminopropylsilanized silica gel for liquid chromatography Prepared for liquid chromatography.

Aminopropylsilanized silica gel for pretreatment Prepared for pretreatment.

L-2-Aminosuberic acid $C_8H_{15}NO_4$ White, crystals or crystalline powder. Odorless.

Optical rotation $[\alpha]_0^{20}$: +19.1 - +20.1° (after drying, 0.1 g, 5 mol/L hydrochloric acid TS, 100 mm).

Loss on drying: not more than 0.3% (1 g, 105°C, 2 hours). Assay—Weigh accurately about 0.3 g of L-2-aminosuberic acid, previously dried, add exactly 6 mL of formic acid to dissolve, then add exactly 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination in the same manner, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS = 18.921 mg of C₈H₁₅NO₄

Ammonia-ammonium acetate buffer solution, pH 8.0 To ammonium acetate TS add ammonia TS dropwise to adjust the pH to 8.0.

Ammonia-ammonium acetate buffer solution, pH 8.5 Dissolve 50 g of ammonium acetate in 800 mL of water and 200 mL of ethanol (95), and add ammonia solution (28) to adjust the pH to 8.5.

Ammonia-ammonium chloride buffer solution, pH 10.0 Dissolve 70 g of ammonium chloride in water, add 100 mL of ammonia solution (28), dilute with water to make 1000 mL, and add ammonia solution (28) dropwise to adjust the pH to 10.0.

Ammonia-ammonium chloride buffer solution, pH 10.7 Dissolve 67.5 g of ammonium chloride in water, add 570 mL of ammonia solution (28), and dilute with water to make 1000 mL.

Ammonia-ammonium chloride buffer solution, pH 11.0 Dissolve 53.5 g of ammonium chloride in water, add 480 mL of ammonia solution (28), and dilute with water to make 1000 mL.

Ammonia-ammonium chloride buffer solution, pH 8.0 Dissolve 1.07 g of ammonium chloride in water to make 100 mL, and adjust the pH to 8.0 by adding diluted ammonia TS (1 in 30).

Ammonia copper TS To 0.5 g of cupric carbonate monohydrate add 10 mL of water, triturate, and add 10 mL of ammonia solution (28).

Ammonia-ethanol TS To 20 mL of ammonia solution (28) add 100 mL of ethanol (99.5).

Ammonia gas NH_3 Prepare by heating ammonia solution (28).

Ammonia-saturated 1-butanol TS To 100 mL of 1-butanol add 60 mL of diluted ammonia solution (28) (1 in 100), shake vigorously for 10 minutes, and allow to stand. Use the upper layer.

Ammonia solution (28) NH₄OH [K 8085, Ammonia Water, Special class, Specific gravity: about 0.90, Density: 0.908 g/mL, Content: 28-30%]

Ammonia TS To 400 mL of ammonia solution (28) add water to make 1000 mL (10%).

Ammonia water See ammonia TS.

1 mol/L Ammonia water To 65 mL of ammonia solution (28) add water to make 1000 mL.

13.5 mol/L Ammonia water To exactly 9 mL of water

add ammonia solution (28) to make exactly 50 mL.

Ammonia water, strong See ammonia solution (28).

Ammonium acetate CH₃COONH₄ [K 8359, Special class]

Ammonium acetate TS Dissolve 10 g of ammonium acetate in water to make 100 mL.

0.5 mol/L Ammonium acetate TS Dissolve 38.5 g of ammonium acetate in water to make 1000 mL.

Ammonium amidosulfate NH₄OSO₂NH₂ [K 8588, Special class]

Ammonium amidosulfate TS Dissolve 1 g of ammonium amidosulfate in water to make 40 mL.

Ammonium aurintricarboxylate See aluminon.

Ammonium carbonate [K 8613, Special class]

Ammonium carbonate TS Dissolve 20 g of ammonium carbonate in 20 mL of ammonia TS and water to make 100 mL.

Ammonium chloride NH₄Cl [K 8116, Special class]

Ammonium chloride-ammonia TS To ammonia solution (28) add an equal volume of water, and saturate this solution with ammonium chloride.

Ammonium chloride buffer solution, pH 10 Dissolve 5.4 g of ammonium chloride in water, and add 21 mL of ammonia solution (28) and water to make 100 mL.

Ammonium chloride TS Dissolve 10.5 g of ammonium chloride in water to make 100 mL (2 mol/L).

Ammonium citrate See diammonium hydrogen citrate.

Ammonium dihydrogenphosphate NH₄H₂PO₄ [K 9006, Special class]

0.02 mol/L Ammonium dihydrogenphosphate TS Dissolve 2.30 g of monobasic ammonium phosphate in water to make 1000 mL.

Ammonium formate $HCOONH_4$ Colorless crystals. Very soluble in water.

Melting point: 116 - 119°C

Ammonium hydrogen carbonate NH₄HCO₃ White or semi-transparency, crystals, crystalline powder or masses, having an ammonia odor.

Ammonium iron (II) sulfate hexahydrate FeSO₄(NH₄)₂SO₄.6H₂O [K 8979, Special class]

Ammonium iron (III) citrate [Same as the monograph Ferric Ammonium Citrate of the Japanese Standards of Food Additives]

Ammonium iron (III) sulfate TS Dissolve 8 g of ammonium iron (III) sulfate 12-water in water to make 100 mL.

Ammonium iron (III) sulfate TS, acidic Dissolve 20 g of ammonium iron (III) sulfate 12-water in a suitable amount of water, add 9.4 mL of sulfuric acid, and add water to make 100 mL.

Ammonium iron (III) sulfate TS, dilute To 2 mL of ammonium iron (III) sulfate TS add 1 mL of 1 mol/L hydrochloric acid TS and water to make 100 mL.

Ammonium iron (III) sulfate 12-water FeNH₄(SO₄)₂.12H₂O [K 8982, Special class]

120

Ammonium molybdate See hexaammonium heptamolybdate tetrahydrate.

Ammonium molybdate-sulfuric acid TS Dissolve 1.0 g of hexaammonium heptamolybdate tetrahydrate in diluted sulfuric acid (3 in 20) to make 40 mL. Prepare before use.

Ammonium molybdate TS Dissolve 21.2 g of hexaammonium heptamolybdate tetrahydrate in water to make 200 mL (10%). Prepare before use.

Ammonium nickel (II) sulfate hexahydrate NiSO₄(NH₄)₂SO₄.6H₂O [K 8990, Special class]

Ammonium nitrate NH₄NO₃ [K 8545, Special class]

Ammonium oxalate See ammonium oxalate monohydrate.

Ammonium oxalate monohydrate (NH₄)₂C₂O₄.H₂O [K 8521, Special class]

Ammonium oxalate TS Dissolve 3.5 g of ammonium oxalate monohydrate in water to make 100 mL (0.25 mol/L).

Ammonium peroxodisulfate (NH₄)₂S₂O₈ [K 8252, Special class]

10% Ammonium peroxodisulfate TS Dissolve 1 g of ammonium peroxodisulfate in water to make 10 mL.

Ammonium persulfate See ammonium peroxodisulfate.

Ammonium polysulfide TS (NH₄)₂S_x [K 8943, Ammonium Sulfide Solution (yellow), First class]

Ammonium sodium hydrogenphosphate tetrahydrate NaNH₄HPO₄. 4H₂O [K 9013, Special class]

Ammonium sulfamate See ammonium amidosulfate.

Ammonium sulfamate TS See ammonium amidosulfate TS.

Ammonium sulfate (NH₄)₂SO₄ [K 8960, Special class]

Ammonium sulfate buffer solution Dissolve 264 g of ammonium sulfate in 1000 mL of water, add 1000 mL of 0.5 mol/L sulfuric acid TS, shake, and filter. The pH of this solution is about 1.

Ammonium sulfide TS $(NH_4)_2S$ [K 8943, Ammonium Sulfide Solution, (colorless), First class] Store in small, well-filled containers, protected from light.

Ammonium tartrate See L-ammonium tartrate.

L-Ammonium tartrate $C_4H_{12}N_2O_6$ [K 8534, (+) Ammonium tartrate, Special class]

Ammonium thiocyanate NH₄SCN [K 9000, Special class]

Ammonium thiocyanate-cobalt (II) nitrate TS Dissolve 17.4 g of ammonium thiocyanate and 2.8 g of cobalt (II) nitrate hexahydrate in water to make 100 mL.

Ammonium thiocyanate TS Dissolve 8 g of ammonium thiocyanate in water to make 100 mL (1 mol/L).

Ammonium vanadate See ammonium vanadate (V).

Ammonium vanadate (V) NH₄VO₃ [K 8747, Special class]

Amygdalin for thin-layer chromatography $C_{20}H_{27}NO_{11}$ A white, odorless powder. Freely soluble in water, sparingly soluble in methanol, and practically insoluble in diethyl ether.

Purity Related substances—Dissolve 0.020 g of amygdalin for thin-layer chromatography in 5 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 10 μ L each of the sample solution and the standard solution as directed in the Identification under Apricot Kernel: any spot other than the principal spot at the Rf value of about 0.5 obtained from the sample solution is not more intense than the spot from the standard solution.

n-Amyl alcohol CH₃(CH₂)₄OH Clear, colorless liquid, having a characteristic odor. Sparingly soluble in water, and miscible with ethanol (95) and with diethyl ether.

Refractive index n_D^{20} : 1.409 – 1.411

Specific gravity d_4^{20} : 0.810 – 0.820

Distilling range: 135 - 140°C, not less than 95 vol%.

t-Amyl alcohol (CH₃)₂C(OH)CH₂CH₃ Clear, color-less liquid, having a characteristic odor. Miscible with *tert*-butanol and with 2-butanone, and freely soluble in water.

Specific gravity d_{20}^{20} : 0.808 – 0.815

Purity Acid and ester—To 20 mL of t-amyl alcohol add 20 mL of ethanol (95) and 5.0 mL of 0.1 mol/L sodium hydroxide VS, and heat gently under a reflux condenser in a water bath for 10 minutes. Cool, add 2 drops of phenolphthalein TS, and titrate with 0.1 mol/L hydrochloric acid VS. Perform a blank determination: not more than 1.25 mL of 0.1 mol/L sodium hydroxide VS is consumed.

Nonvolatile residue—Evaporate 50 mL of t-amyl alcohol, and dry at 105°C for 1 hour: the residue is not more than 1.6 mg.

Distilling range: 100 - 103°C, not less than 95 vol%.

tert-Amyl alcohol See t-amyl alcohol.

Amyl alcohol, iso See 3-methyl-1-butanol.

Anesthetic ether See ether, anesthetic.

Anhydrous caffeine See caffeine, anhydrous.

Anhydrous cupric sulfate See copper (II) sulfate (anhydrous).

Anhydrous dibasic sodium phosphate See disodium hydrogenphosphate.

Anhydrous dibasic sodium phosphate for pH determination See disodium hydrogenphosphate for pH determination.

Anhydrous lactose $C_{12}H_{22}O_{11}$ [Same as the monograph Anhydrous Lactose]

Anhydrous potassium carbonate See potassium carbonate.

Anhydrous sodium acetate See sodium acetate, anhydrous.

Anhydrous sodium carbonate See sodium carbonate, anhydrous.