

Each mL of 0.005 mol/L sulfuric acid VS
= 1.7122 mg of $C_7H_9NO_2S$

***p*-Toluene sulfonamide** $CH_3C_6H_4SO_2NH_2$ White, crystals or crystalline powder. Melting point: about 137°C

Purity Related substances—Dissolve 0.030 g of *p*-toluene sulfonamide in acetone to make exactly 200 mL. Proceed with 10 μ L of this solution as directed in the Purity (3) under Tolazamide: any spot other than the principal spot at the *R_f* value of about 0.6 does not appear.

***p*-Toluene sulfonic acid** See *p*-toluenesulfonic acid monohydrate.

***p*-Toluenesulfonic acid monohydrate**
 $CH_3C_6H_4SO_3H \cdot H_2O$ [K 8681, Special class]

***o*-Toluic acid** $C_8H_8O_2$ White, crystals or crystalline powder.

Melting point: 102 – 105°C

Content: not less than 98.0%.

Toluidine blue $C_{15}H_{16}ClN_3S$ Dark green powder, soluble in water, and slightly soluble in ethanol (95).

Triamcinolone acetonide $C_{24}H_{31}FO_6$ [Same as the namesake monograph]

Trichloroacetic acid CCl_3COOH [K 8667, Special class]

Trichloroacetic acid-gelatin-tris buffer solution To 1 volume of a solution of trichloroacetic acid (1 in 5) add 6 volume of gelatin-tris buffer solution, pH 8.0 and 5 volume of water.

Trichloroacetic acid TS Dissolve 1.80 g of trichloroacetic acid, 2.99 g of sodium acetate trihydrate and 1.98 g of acetic acid (31) in water to make 100 mL.

1,1,2-Trichloro-1,2,2-trifluoroethane $CFCl_2 \cdot CF_2Cl$
Colorless volatile liquid. Miscible with acetone and with diethyl ether, and not with water.

Purity Related substances—Perform the test with 0.1 μ L of 1,1,2-trichloro-1,2,2-trifluoroethane as directed under the Gas Chromatography according to the operating conditions in the Purity (5) under Halothane: any peak other than the peak of 1,1,2-trichloro-1,2,2-trifluoroethane does not appear.

Triethanolamine See 2,2',2''-nitrilotrisethanol.

Triethylamine $(C_2H_5)_3N$ Clear colorless liquid, having a strong amines odor. Miscible with methanol, with ethanol (95) and with diethyl ether.

Specific gravity d_4^{20} : 0.722 – 0.730

Melting point: 89 – 90°C

Triethylamine-phosphate buffer solution, pH 5.0 To 1.0 mL of triethylamine add 900 mL of water, adjust the pH to 5.0 with diluted phosphoric acid (1 in 10), and add water to make 1000 mL.

Trifluoroacetic acid CF_3COOH Colorless, clear liquid, having a pungent odor. Miscible well with water.

Boiling point: 72 – 73°C

Specific gravity d_{20}^{20} : 1.535

Trifluoroacetic acid for nuclear magnetic resonance spec-

troscopy CF_3COOH Prepared for nuclear magnetic resonance spectroscopy.

Trifluoroacetic acid TS To 1 mL of trifluoroacetic acid add water to make 1000 mL.

Trifluoroacetic anhydride for gas chromatography $(CF_3CO)_2O$ Colorless, clear liquid, having a pungent odor.

Trimethylsilyl imidazole $C_6H_{12}N_2Si$ Clear, colorless to pale yellow liquid.

Refractive index n_D^{20} : 1.4744 – 1.4764

2,4,6-Trinitrobenzenesulfonic acid
 $C_6H_2(NO_2)_3SO_3H \cdot 2H_2O$ Pale yellow to light yellow powder.

Water: 11 – 15% (0.1 g, volumetric titration, direct titration).

Content: not less than 98%, calculated on the anhydrous basis. Assay—Weigh accurately about 0.3 g of 2,4,6-trinitrobenzenesulfonic acid, dissolve in 50 mL of a mixture of water and ethanol (99.5) (1:1), and titrate with 0.1 mol/L sodium hydroxide VS (potentiometric titration). Perform a blank determination and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 29.317 mg of $C_6H_2(NO_2)_3SO_3H$

2,4,6-Trinitrophenol $HOC_6H_2(NO_2)_3$ [K 8759: 1984, Special class]. Preserve in tight containers, in a cold place, remote from fire.

2,4,6-Trinitrophenol-ethanol TS Dissolve 1.8 g of 2,4,6-trinitrophenol in 50 mL of diluted ethanol (99.5) (9 in 10) and 30 mL of water, and add water to make 100 mL.

2,4,6-Trinitrophenol TS Dissolve 1 g of 2,4,6-trinitrophenol in 100 mL of hot water, cool, and filter if necessary.

2,4,6-Trinitrophenol TS, alkaline Mix 20 mL of 2,4,6-trinitrophenol TS with 10 mL of a solution of sodium hydroxide (1 in 20), and add water to make 100 mL. Use within 2 days.

Triphenylchloromethane $(C_6H_5)_3CCl$ [K 8674: 1978, Special class]

Triphenyltetrazolium chloride See 2,3,5-triphenyl-2*H*-tetrazolium.

Triphenyltetrazolium chloride TS See 2,3,5-triphenyl-2*H*-tetrazolium.

2,3,5-Triphenyl-2*H*-tetrazolium chloride $C_{19}H_{15}ClN_4$
[K 8214, Special class]

2,3,5-Triphenyl-2*H*-tetrazolium chloride TS Dissolve 0.25 g of 2,3,5-triphenyl-2*H*-tetrazolium chloride in ethanol (99.5) to make 100 mL. Prepare before use.

Tris buffer solution, pH 7.0 Dissolve 24.3 g of 2-amino-2-hydroxymethyl-1,3-propanediol in 1000 mL of water, and adjust the pH to 7.0 with 0.1 mol/L hydrochloric acid TS.

0.05 mol/L Tris buffer solution, pH 7.0 Dissolve 6.06 g of 2-amino-2-hydroxymethyl-1,3-propanediol in about 750 mL of water, adjust to pH 7.0 with 1 mol/L hydrochloric acid TS, and add water to make 1000 mL.

0.1 mol/L Tris buffer solution, pH 8.0 Dissolve 2.42 g of 2-amino-2-hydroxymethyl-1,3-propanediol in 100 mL of water, adjust the pH to 8.0 with 0.2 mol/L hydrochloric acid TS, and add water to make 200 mL.

Tris buffer solution, pH 8.2 Dissolve 24.2 g of 2-amino-2-hydroxymethyl-1,3-propanediol and 0.5 g of polysorbate 20 in 800 mL of water, adjust to pH 8.2 with 1 mol/L hydrochloric acid TS, and add water to make 1000 mL.

Tris buffer solution, pH 9.5 Dissolve 36.3 g of 2-amino-2-hydroxymethyl-1,3-propanediol in 1000 mL of water, and adjust the pH to 9.5 by adding 1 mol/L hydrochloric acid TS.

Tris buffer solution for bacterial endotoxins test Dissolve 18.2 g of 2-amino-2-hydroxymethyl-1,3-propanediol in 800 mL of water for bacterial endotoxins test, add 100 mL of 0.1 mol/L hydrochloric acid TS and water for bacterial endotoxins test to make 1000 mL, and sterilize by heating in an autoclave at 121°C for 90 minutes.

Trishydroxymethylaminomethane See 2-amino-2-hydroxymethyl-1,3-propanediol.

Trisodium citrate dihydrate $C_6H_5Na_3O_7 \cdot 2H_2O$ [K 8288, or same as the monograph Sodium Citrate]

Trisodium ferrous pentacyanoamine TS To 1.0 g of sodium pentacyanonitrosylferrate (III) dihydrate add 3.2 mL of ammonia TS, shake, and allow to stand in a tightly stoppered bottle for a night in a refrigerator. Add this solution to 10 mL of ethanol (99.5), filter to collect the yellow precipitate yielded with suction. Wash the precipitate with dehydrated diethyl ether, dry the precipitate, and keep in a desiccator. Dissolve the precipitate in water to make a 1.0 mg/mL solution before use, and keep in a refrigerator. Use within a week after preparation.

Trisodium phosphate 12-water $Na_3PO_4 \cdot 12H_2O$ [K 9012, Special class]

Trypsin for liquid chromatography An enzyme obtained from the bovine pancreas. This one part digests 250 parts of casein in the following reaction system.

Casein solution—To 0.1 g of milk casein add 30 mL of water, disperse the casein well, add 1.0 mL of diluted sodium hydroxide TS (1 in 10) to dissolve, and add water to make 50 mL. Prepare before use.

Sample solution—Dissolve 0.01 g of trypsin for liquid chromatography in 500 mL of water.

Procedure—To 5 mL of the casein solution add 2 mL of the sample solution and 3 mL of water, mix, then allow to stand at 40°C for 1 hour, and add 3 drops of a mixture of ethanol (95), water and acetic acid (100) (10:9:1): no precipitate appears.

Trypsin inhibitor Produced by purifying soybean. Each mg of trypsin inhibitor inhibits 10,000 to 30,000 BAEE Units of trypsin. One BAEE Unit means a trypsin activity to indicate an absorbance difference of 0.001 at 253 nm when 3.2 mL of the solution is reacted at 25°C and pH 7.6, using *N*- α -benzoyl-L-arginine ethyl ester as substrate.

Trypsin inhibitor TS Dissolve 5 mg of trypsin inhibitor in 0.05 mol/L phosphate buffer solution, pH 7.0 to make 10 mL.

Trypsin TS for test of elcatonin Dissolve 5 mg of trypsin

for liquid chromatography in 20 mL of a solution of ammonium hydrogen carbonate (1 in 100). Prepare before use.

Trypsin TS for test of ulinastatin Dissolve crystal trypsin for ulinastatin assay in ice-cooled 1 mmol/L hydrochloric acid TS containing 1 mmol/L calcium chloride dihydrate so that each mL of the solution contains 180 μ g of trypsin. Prepare before use, and preserve in an ice-cooled water bath.

L-Tryptophan $C_{11}H_{12}N_2O_2$ [Same as the namesake monograph]

Turmeric paper Macerate 20 g of powdered turmeric, the dried root of *Curcuma longa* Linné, with four 100 mL- portions of cold water, decant the supernatant liquid each time, and discard it. Dry the residue at a temperature not over 100°C. Macerate the dried residue with 100 mL of ethanol (95) for several days, and filter. Immerse filter paper in this ethanol decoction, and allow the ethanol (95) to evaporate spontaneously in clean air.

Sensitivity—Dip a strip of turmeric paper, about 1.5 cm length, in a solution of 1 mg of boric acid in a mixture of 1 mL of hydrochloric acid and 4 mL of water, after 1 minute remove the paper from the liquid, and allow it to dry spontaneously: the yellow color changes to brown. When the strip is moistened with ammonia TS, the color of the strip changes to greenish black.

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

L-Tyrosine $C_9H_{11}NO_3$ [K 9049, Special class]

Ubiquinone-9 Yellow to orange, crystalline powder. Odorless and no taste.

Melting point: about 44°C

Absorbance $E_{1\text{ cm}}^{1\%}$ (275 nm): 163 – 190 (ethanol (99.5))

Uracil $C_4H_4N_2O_2$ Needle crystals. Freely soluble in hot water, and slightly soluble in cold water.

Melting point: 335°C

Uranyl acetate See uranyl acetate dihydrate.

Uranyl acetate dihydrate $UO_2(CH_3COO)_2 \cdot 2H_2O$ [K 8360: 1961, Special class]

Uranyl acetate TS Dissolve 1 g of uranyl acetate dihydrate in water to make 20 mL, and filter if necessary.

Uranyl acetate-zinc TS Dissolve 10 g of uranyl acetate dihydrate in 5 mL of acetic acid (31) and 50 mL of water by heating. Separately, dissolve 30 g of zinc acetate dihydrate in 3 mL of acetic acid (31) and 30 mL of water by heating. While the two solutions are still warm, mix them, cool, and filter.

Urea H_2NCONH_2 [K 8731, Special class]

Urethane See ethyl carbamate.

***n*-Valerianic acid** $CH_3(CH_2)_3COOH$ Clear, colorless to pale yellow liquid, having a characteristic odor. Miscible with ethanol (95) and with diethyl ether, and soluble in water.

Specific gravity d_4^{20} : 0.936 – 0.942

Distilling range: 186 – 188°C, not less than 98 vol%.

L-Valine $C_5H_{11}NO_2$ [Same as the namesake mono-

graph]

H-D-Valyl-L-leucyl-L-arginine *p*-nitroanilide dihydrochloride $C_{23}H_{38}N_8O_5 \cdot 2HCl$ White to pale yellow, powder or masses. Sparingly soluble in water.

Absorbance $E_{1\text{cm}}^{1\%}$ (316 nm): 214 – 236 (0.01 g, water, 500 mL).

Vanadium pentoxide See vanadium (V) oxide.

Vanadium pentoxide TS See vanadium (V) oxide TS.

Vanadium pentoxide TS, dilute See vanadium (V) oxide TS, dilute.

Vanadium (V) oxide V_2O_5 [K 8343: 1963, Special class]

Vanadium (V) oxide TS Add vanadium (V) oxide to phosphoric acid, saturate with vanadium (V) oxide by shaking vigorously for 2 hours, and filter through a glass filter.

Vanadium (V) oxide TS, dilute Dilute 10 mL of vanadium (V) oxide TS with water to make 100 mL. Prepare before use.

Vanillin $C_6H_3CHO(OCH_3)(OH)$ [K 9544]

Vanillin-hydrochloric acid TS Dissolve 5 mg of vanillin in 0.5 mL of ethanol (95), and to this solution add 0.5 mL of water and 3 mL of hydrochloric acid. Prepare before use.

Vanillin-sulfuric acid-ethanol TS Dissolve 3 g of vanillin in ethanol (99.5) to make 100 mL, and add 0.5 mL of sulfuric acid.

Vanillin-sulfuric acid TS Add cautiously 75 mL of sulfuric acid to 25 mL of ice-cold ethanol (95). After cooling, add 1 g of vanillin to dissolve. Prepare before use.

Vegetable oil Vegetative oils specified in monographs.

Vinblastine sulfate $C_{46}H_{58}N_4O_9 \cdot H_2SO_4$ [Same as the namesake monograph]

Vincristine sulfate $C_{46}H_{56}N_4O_{10} \cdot H_2SO_4$ [Same as the namesake monograph]

Vinyl acetate $C_4H_6O_2$ Clear, colorless liquid.

Specific gravity: 0.932 – 0.936

Water: not more than 0.2%

Vinyl chloride C_2H_3Cl Colorless gas.

Melting point: $-160^\circ C$

Boiling point: $-14^\circ C$

1-Vinyl-2-pyrrolidone C_6H_9NO Clear liquid.

Purity—Perform the test with 0.5 μL of 1-vinyl-2-pyrrolidone as directed under the Gas Chromatography according to the following conditions. Determine each peak area of the solutions by the automatic integration method, and calculate the amount of 1-vinyl-2-pyrrolidone by the area percentage method: it is not less than 99.0%.

Operating conditions

Detector: A hydrogen flame-ionization detector.

Column: A hollow, capillary glass column about 0.53 mm in inside diameter and about 30 m in length, having an about 1.0- μm layer of polyethylene glycol 20 M for gas chromatography on the inner side.

Column temperature: Maintain the temperature at $80^\circ C$ for 1 minute, then raise at the rate of $10^\circ C$ per minute to $190^\circ C$, and hold constant to the temperature for 20

minutes.

Temperature of sample vaporization chamber: A constant temperature of about $190^\circ C$.

Carrier gas: Helium

Flow rate: Adjust the flow rate so that the retention time of 1-vinyl-2-pyrrolidone is about 15 minutes.

Detection sensitivity: Adjust the detection sensitivity so that the peak height of 1-vinyl-2-pyrrolidone from 0.5 μL of 1-vinyl-2-pyrrolidone is about 70% of the full scale.

Time span of measurement: About twice as long as the retention time of 1-vinyl-2-pyrrolidone after the solvent peak.

Water—Take 50 mL of methanol for Karl Fischer method and 10 mL of butyrolactone in a dry titration flask, and titrate with Karl Fischer TS until end point. Weigh accurately about 2.5 g of 1-vinyl-2-pyrrolidone, transfer immediately to a titration flask, and perform the test: water is not more than 0.1%.

V8 protease A protease obtained from *Staphylococcus aureus* strain. When an amount of the enzyme hydrolyzes 1 μmol of *N*-*t*-butoxycarbonyl-L-glutamic acid- α -phenyl ester in 1 minute at pH 7.8 and $37^\circ C$ is defined as 1 unit, it contains 500 – 1000 units per mg.

V8 protease TS Dissolve V8 protease in water to make a solution of 1 mg/mL. Keep at a cold place and use within 6 days after preparation.

Warfarin potassium for assay [Same as the monograph Warfarin Potassium. When dried, it contains not less than 99.0% of warfarin potassium ($C_{19}H_{15}KO_4$).]

25% Water containing benzoyl peroxide See Benzoyl peroxide, 25% water containing.

Water for bacterial endotoxins test [Same as the monograph Water for Injection in Part II or water produced by other procedures that shows no reaction with the lysate reagent employed, at the detection limit of the reagent.]

Water for injection [Same as the namesake monograph in Part II]

Weakly acidic CM-bridged cellulose cation exchanger (H type) Weakly acidic cation exchanger, intensified by crosslinking porous spherical cellulose, into which carboxymethyl groups have been introduced.

Wijs' TS Transfer 7.9 g of iodine trichloride and 8.9 g of iodine to separate flasks, dissolve each with acetic acid (100), mix both solutions, and add acetic acid (100) to make 1000 mL. Preserve in light-resistant, glass containers.

Xanthene $C_{13}H_{10}O$ White to light yellow crystals or crystalline powder, having a slight, characteristic odor.

Melting point: $98 - 102^\circ C$

Water: not more than 0.5% (0.15 g).

Xanthene-9-carboxylic acid $C_{14}H_{10}O_3$ Dissolve 0.25 g of propantheline bromide in 5 mL of water and 10 mL of sodium hydroxide TS, heat the mixture to boiling, then continue to heat for 2 minutes. Cool to $60^\circ C$, add 5 mL of dilute sulfuric acid, cool, filter the precipitate, and wash thoroughly with water. Recrystallize the residue from dilute ethanol, and dry for 3 hours in a desiccator (in vacuum, silica gel).

Melting point: $217 - 222^\circ C$

Xanthone $C_{13}H_8O_2$ Light yellow powder. Freely soluble in chloroform, and slightly soluble in hot water and in diethyl ether.

Melting point: 174 – 176°C

Purity Related substances—Dissolve 0.050 g of xanthone in chloroform to make exactly 10 mL. Perform the test with 5 μ L of this solution as directed in the Purity under Propantheline Bromide: any spot other than the principal spot at the *Rf* value of about 0.7 does not appear.

Xanthidrol $C_{13}H_{10}O_2$ White to pale yellow powder. Dissolves in ethanol (95), in diethyl ether, in chloroform, and in acetic acid (100), and is practically insoluble in water.

Melting point: 121 – 124°C

Residue on ignition: not more than 2.0% (0.5 g).

Xylene $C_6H_4(CH_3)_2$ [K 8271, First class]

o-Xylene $C_6H_4(CH_3)_2$ Colorless, clear liquid.

Refractive index n_D^{20} : 1.501 – 1.506

Specific gravity d_4^{20} : 0.875 – 0.885

Distilling range: 143 – 146°C, not less than 95 vol%.

Xylene cyanol FF $C_{25}H_{27}N_2NaO_7S_2$ [K 8272, Special class]

Xylenol orange $C_{31}H_{30}N_2Na_2O_{13}S$ [K 9563, Special class]

Xylenol orange TS Dissolve 0.1 g of xylenol orange in water to make 100 mL.

Xylitol $C_5H_{12}O_5$ [Same as the namesake monograph]

Xylose See D-xylose.

D-Xylose $C_5H_{10}O_5$ [Same as the monograph D-Xylose of the Japanese Standards of Food Additives]

Yeast extract A peptone-like substance which represents all the soluble product of yeast cells (*Saccharomyces*) prepared under optimum conditions, clarified, and dried by evaporating to a powder. Yeast extract (1 g) represents not less than 7.5 g of yeast. A reddish yellow to brown powder, having a characteristic but not putrescent odor. Soluble in water, forming a yellow to brown solution, having a slight acidic reaction. It contains no added carbohydrate.

Purity (1) Chloride (calculated as NaCl): not more than 5%.

(2) Coagulable protein—On heating a solution of yeast extract (1 in 20) to boiling, no precipitate is produced.

Loss on drying: not more than 5% (105°C, constant mass).

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

Nitrogen content: 7.2 – 9.5% (105°C, constant mass, after drying, according to the Nitrogen Determination).

Yellow beeswax [Same as the namesake monograph in Part II]

Yellow mercuric oxide See mercury (II) oxide, yellow.

Yellow mercury (II) oxide See mercury (II) oxide, yellow.

Zeolite for gas chromatography (0.5 nm in pore diameter) Zeolite prepared for gas chromatography.

Zinc Zn [K 8012, Special class]

Zinc acetate See zinc acetate dihydrate.

Zinc acetate dihydrate $Zn(CH_3COO)_2 \cdot 2H_2O$ [K 8356, Special class]

Zinc, arsenic-free See zinc for arsenic analysis.

Zinc chloride $ZnCl_2$ [K 8111, Special class]

Zinc chloride TS Dissolve 10 g of zinc chloride and 10 g of potassium hydrogen phthalate in 900 mL of water, adjust the pH to 4.0 with sodium hydroxide TS, and add water to make 1000 mL.

Zinc disodium ethylenediamine tetraacetate See zinc disodium ethylenediamine tetraacetate tetrahydrate.

Zinc disodium ethylenediamine tetraacetate tetrahydrate $C_{10}H_{12}ZnN_2Na_2O_8 \cdot 4H_2O$ White powder. The pH of a solution of zinc disodium ethylenediamine tetraacetate (1 in 100) is between 6.0 and 9.0.

Purity Clarity and color of solution—Dissolve 0.10 g of zinc disodium ethylenediamine tetraacetate tetrahydrate in 10 mL of freshly boiled and cooled water: the solution is clear and colorless.

Content: not less than 98.0%. Assay—Dissolve about 0.5 g of zinc disodium ethylenediamine tetraacetate tetrahydrate, accurately weighed, in water to make exactly 100 mL. Pipet 10 mL of this solution, adjust the pH to about 2 with 80 mL of water and dilute nitric acid, and titrate with 0.01 mol/L bismuth nitrate VS until the color of the solution changes from yellow to red (indicator: 2 drops of xylenol orange TS).

Each mL of 0.01 mol/L bismuth nitrate VS
= 4.716 mg of $C_{10}H_{12}ZnN_2Na_2O_8 \cdot 4H_2O$

Zinc dust See zinc powder.

Zinc for arsenic analysis Zn [K 8012] Use granules of about 800 μ m.

Zinc iodide-starch paper Impregnate the filter paper for volumetric analysis with freshly prepared zinc iodide-starch TS, and dry in the clean room. Preserve in a glass-stoppered bottle, protected from light and moisture.

Zinc iodide-starch TS To 100 mL of boiling water add a solution of 0.75 g of potassium iodide in 5 mL of water, a solution of 2 g of zinc chloride in 10 mL of water and a smooth suspension of 5 g of starch in 30 mL of water, with stirring. Continue to boil for 2 minutes, then cool.

Sensitivity—Dip a glass rod into a mixture of 1 mL of 0.1 mol/L sodium nitrite VS, 500 mL of water and 10 mL of hydrochloric acid, and touch on zinc iodide-starch paste TS: an apparently blue color appears.

Storage—Preserve in tightly stoppered bottles, in a cold place.

Zincon $C_{20}H_{16}N_4O_6S$ [K 9517, Special class]

Zincon TS Dissolve 0.1 g of zincon in 2 mL of 1 mol/L sodium hydroxide VS, and add water to make 100 mL.

Zinc powder Zn [K 8013, Special class]

Zinc (standard reagent) Zn [K 8005, Standard reagent for volumetric analysis]

Zinc sulfate See zinc sulfate heptahydrate.