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make 1000 mL.

Terephthalic acid $C_6H_4(COOH)_2$ White crystals or crystalline powder. Slightly soluble in ethanol (95), and practically insoluble in water and ether.

Residue on ignition: not more than 0.3% (1 g).

Content: not less than 95.0%. Assay—Weigh accurately about 2 g of terephthalic acid, dissolve in exactly 50 mL of 1 mol/L sodium hydroxide VS, and titrate with 1 mol/L hydrochloric acid VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination in the same manner.

Each mL of 1 mol/L sodium hydroxide VS = 83.07 mg of $C_8H_6O_4$

Terephthalic acid for gas chromatography

C₆H₄(COOH)₂ Terephthalic acid prepared for gas chromatography.

Terphenyl $C_{18}H_{14}$ White crystalline powder.

Melting point: 208 - 213°C

Identification—Determine the absorption spectrum of a solution of terphenyl in methanol (1 in 250,000) as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 276 and 280 nm.

p-Terphenyl See terphenyl.

Testosterone propionate $C_{22}H_{32}O_3$ [Same as the name-sake monograph]

Test solution for water determination See the Water Determination under the General Tests, Processes and Apparatus

Tetrabromophenolphthalein ethyl ester potassium salt $C_{22}H_{13}O_4Br_4K$ [K 9042, Special class]

Tetrabromophenolphthalein ethyl ester TS Dissolve 0.1 g of tetrabromophenolphthalein ethyl ester potassium salt in acetic acid (100) to make 100 mL. Prepare before use.

Tetra *n*-butylammonium bromide $[CH_3(CH_2)_3]_4NBr$ White, crystals or crystalline powder, having a slight, characteristic odor.

Melting point: 101 - 105°C

Purity Clarity and color of solution—Dissolve 1.0 g of tetra *n*-butylammonium bromide in 20 mL of water: the solution is clear and colorless.

Content: not less than 98.0%. Assay—Dissolve about 0.5 g of tetra n-butylammonium bromide, accurately weighed, in 50 mL of water, add 5 mL of dilute nitric acid, and titrate with 0.1 mol/L silver nitrate VS while strongly shaking (potentiometric titration). Perform a blank determination and make any necessary correction.

Each mL of 0.1 mol/L silver nitrate VS = 32.237 mg of $C_{16}H_{36}NBr$

Tetra *n*-butylammonium chloride $C_{16}H_{36}ClN$ White crystals, and it is deliquescent.

Water: not more than 6.0% (0.1 g).

Content: not less than 95.0%, calculated on the anhydrous basis. Assay—Weigh accurately about 0.25 g of tetra n-butylammonium chloride, dissolve in 50 mL of water, and titrate with 0.1 mol/L silver nitrate VS (potentiometric titration).

Each mL of 0.1 mol/L silver nitrate VS = 27.792 mg of $C_{16}H_{36}ClN$

Tetrabutylammonium hydrogensulfate $C_{16}H_{37}NO_4S$ White crystalline powder.

Content: not less than 98.0%. Assay—Weigh accurately about 0.7 g of tetrabutylammonium hydrogensulfate, dissolve in 100 mL of freshly boiled and cooled water, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of bromocresol green-methyl red TS).

Each mL of 0.1 mol/L sodium hydroxide VS = 33.954 mg of $C_{16}H_{37}NO_4S$

40% Tetrabutylammonium hydroxide TS A solution containing 40 g/dL of tetrabutylammonium hydroxide $[(C_4H_9)_4NOH: 259.48]$.

Content: 36 - 44 g/dL. Assay—Pipet 10 mL of 40% tetrabutylammonium hydroxide TS, and titrate with 1 mol/L hydrochloric acid VS (indicator: 3 drops of methyl red TS).

Each mL of 1 mol/L hydrochloric acid VS = 259.48 mg of $C_{16}H_{37}NO$

0.005 mol/L Tetrabutylammonium hydroxide TS To 10 mL of tetrabutylammonium hydroxide TS add 700 mL of water, adjust to pH 4.0 with diluted phosphoric acid (1 in 10), and add water to make 1000 mL.

Tetrabutylammonium hydroxide-methanol TS Methanol solution containing 25 g/dL of tetrabutylammonium hydroxide [$(C_4H_9)_4NOH$: 259.48]. Colorless to pale yellow solution, having an ammonium-like odor.

Content: 22.5 – 27.5 g/dL. Assay—Pipet 15 mL of tetrabutylammonium hydroxide-methanol TS and titrate with 1 mol/L hydrochloric acid VS (indicator: 3 drops of methyl red TS).

Each mL of 1 mol/L hydrochloric acid VS = 259.48 mg of $C_{16}H_{37}NO$

10% Tetrabutylammonium hydroxide-methanol TS

A methanol solution containing 10 g/dL of tetrabutylammonium hydroxide [$(C_4H_9)_4$ NOH: 259.48].

Content: 9.0 – 11.0 g/dL. Assay—Pipet 2 mL of 10% tetrabutylammonium hydroxide-methanol TS, transfer to a glass-stoppered flask containing 20 mL of water, and titrate with 0.1 mol/L hydrochloric acid VS (indicator: 3 drops of methyl red TS).

Each mL of 0.1 mol/L hydrochloric acid VS = 25.948 mg of C₁₆H₃₇NO

Tetrabutylammonium hydroxide TS A solution containing 13 g/dL of tetrabutylammonium hydroxide $[(C_4H_9)_4]$ NOH: 259.48].

Content: 11.7 - 14.3 g/dL. Assay—Pipet a quantity, equivalent to about 0.3 g of tetrabutylammonium hydroxide [(C₄H₉)₄NOH], transfer to a glass-stoppered flask containing 15 mL of water, accurately weighed, and titrate with 0.1 mol/L hydrochloric acid VS (indicator: 3 drops of methyl red TS).

Each mL of 0.1 mol/L hydrochloric acid VS = 25.948 mg of $C_{16}H_{37}NO$

Tetrabutylammonium phosphate $(C_4H_9)_4NH_2PO_4$ White powder. It is soluble in water.

Content: not less than 97.0%. Assay—Weigh accurately 1.5 g of tetrabutylammonium phosphate, dissolve in 80 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 = 169.73 mg of $(C_4H_9)_4NH_2PO_4$

Tetracycline $C_{22}H_{24}N_2O_8$ [Same as the monograph Tetracycline]

Tetraethylammonium hydroxide TS (C₂H₅)₄NOH [K 8650: 1964, Tetraethylammonium hydroxide solution (10%), Special class]

Tetra-n-heptylammonium bromide [CH₃(CH₂)₆]₄NBr White, crystals or crystalline powder, having a slight, characteristic odor.

Melting point: 87 - 89°C.

Content: not less than 98.0%. Assay—Dissolve about 0.5 g of tetra-n-heptylammonium bromide, accurately weighed, in 50 mL of diluted acetonitrile (3 in 5), and 5 mL of dilute nitric acid, and titrate with 0.1 mol/L silver nitrate VS while strongly shaking (potentiometric titration). Perform a blank determination and make any necessary correction.

Each mL of 0.1 mol/L silver nitrate VS = $49.02 \text{ mg } C_{28}H_{60}NBr$

Tetrahydrofuran CH₂(CH₂)₂CH₂O [K 9705, Special class]

Tetrahydrofuran for gas chromatography Use tetrahydrofuran prepared by distilling with iron (II) sulfate heptahydrate.

Storage—Preserve in containers, in which the air has been displaced by nitrogen, in a dark, cold place.

Tetrahydroxyquinone $C_6H_4O_6$ Dark blue crystals. Its color changes to yellow on exposure to light. Soluble in ethanol (95) and sparingly soluble in water.

Tetrahydroxyquinone indicator Mix 1 g of tetrahydroxyquinone with 100 g of sucrose homogeneously.

Tetramethylammonium hydroxide (CH₃)₄NOH Ordinarily, available as an approximately 10% aqueous solution, which is clear and colorless, and has a strong ammonia-like odor. Tetramethylammonium hydroxide is a stronger base than ammonia, and rapidly absorbs carbon dioxide from the air. Use a 10% aqueous solution.

Purity Ammonia and other amines—Weigh accurately a quantity of the solution, corresponding to about 0.3 g of tetramethylammonium hydroxide [(CH₃)₄NOH], in a weighing bottle already containing 5 mL of water. Add a slight excess of 1 mol/L hydrochloric acid TS (about 4 mL), and evaporate on a water bath to dryness. The mass of the residue (tetramethylammonium chloride), dried at 105° C for 2 hours and multiplied by 0.8317, represents the quantity of tetramethylammonium hydroxide [(CH₃)₄NOH], and corresponds to $\pm 0.2\%$ of that found in the Assay.

Residue on evaporation: not more than 0.02% (5 mL, 105°C, 1 hour).

Content: not less than 98% of the labeled amount. Assay—Accurately weigh a glass-stoppered flask containing about 15 mL of water. Add a quantity of the solution, equivalent to about 0.2 g of tetramethylammonium hydroxide [(CH₃)₄NOH], weigh again, and titrate with 0.1 mol/L hydrochloric acid VS (indicator: methyl red TS).

Each mL of 0.1 mol/L hydrochloric acid VS = 9.115 mg of $C_4H_{13}NO$

Tetramethylammonium hydroxide-methanol TS A methanol solution containing of 10 g/dL of tetramethylammonium hydroxide [(CH₃)₄NOH: 91.15]

Content: 9.0 - 11.0 g/dL. Assay—Pipet 2 mL of tetramethylammonium hydroxide-methanol TS, transfer to a glass-stoppered flask containing 20 mL of water, and titrate with 0.1 mol/L hydrochloric acid VS (indicator: bromocresol green-methyl red TS).

Each mL of 0.1 mol/L hydrochloric acid VS = 9.115 mg of $C_4H_{13}NO$

Tetramethylammonium hydroxide TS Pipet 15 mL of tetramethylammonium hydroxide, and add dehydrated ethanol (99.5) to make exactly 100 mL.

Tetramethylammonium hydroxide TS, pH 5.5 To 10 mL of tetramethylammonium hydroxide add 990 mL of water, and adjust the pH to 5.5 with diluted phosphoric acid (1 in 10).

N,N,N',N'-Tetramethylethylenediamine (CH₃)₂NCH₂CH₂N(CH₃)₂ Pale yellow clear liquid. Specific gravity d₄²⁰: 0.774 - 0.799 Content: not less than 99.0%.

Tetramethylsilane for nuclear magnetic resonance spectroscopy $(CH_3)_4Si$ Prepared for nuclear magnetic resonance spectroscopy.

Tetra *n*-pentylammonium bromide [CH₃(CH₂)₄]₄NBr White, crystals or crystalline powder. It is hygroscopic. *Melting point*: 100 – 101°C

Tetraphenylboron potassium TS Add 1 mL of acetic acid (31) to a solution of potassium biphthalate (1 in 500), then to this solution add 20 mL of a solution of tetraphenylboron sodium (7 in 1000), shake well, and allow to stand for 1 hour. Collect the produced precipitate on filter paper, and wash it with water. To 1/3 quantity of the precipitate add 100 mL of water, warm, with shaking, at about 50°C for 5 minutes, cool quickly, allow to stand for 2 hours with occasional shaking, and filter, discarding the first 30 mL of the filtrate.

Tetraphenylboron sodium See sodium tetraphenylborate.

Theophylline $C_7H_8N_4O_2$ White powder. Slightly soluble in water.

Melting point: 269 – 274°C

Purity Caffeine, theobromine or paraxanthine—To 0.20 g of theophylline add 5 mL of potassium hydroxide TS or 5 mL of ammonia TS: each solution is clear.

Loss on drying: not more than 0.5% (1 g, 105°C, 4 hours). Content: not less than 99.0%. Assay—Weigh accurately about 0.25 g of theophylline, previously dried, dissolve it in 40 mL of N,N-dimethylformamide, and titrate with 0.1 mol/L sodium methoxide VS (indicator: 3 drops of thymol blue-N,N-dimethylformamide TS). Perform a blank determination and make any necessary correction.

Each mL of 0.1 mol/L sodium methoxide VS = 18.017 mg of $C_7H_8N_4O_2$

Thiamine nitrate $C_{12}H_{17}N_5O_4S$ [Same as the namesake monograph]

Thianthol [Same as the monograph Thianthol. Proceed as directed for Identification (3) under Sulfur, Salicylic Acid and Thianthol Ointment: any spot other than the principal spot does not appear.]

3-Thienylethylpenicillin sodium $C_{14}H_{15}N_2NaO_4S_2$ White to pale yellowish white powder. Very soluble in water, freely soluble in methanol, and sparingly soluble in ethanol (95).

Water: Not more than 10.0% (0.2 g, volumetric titration, direct titration).

Optical rotation $[\alpha]_D^{20}$: $+265 - +290^{\circ}$ (0.5 g calculated on the anhydrous bases, water, 50 mL, 100 mm).

Content: not less than 90% calculated on the anhydrous basis. Assay—Weigh accurately about 0.1 g of 3-thienylethylpenicillin sodium, dissolve in 35 mL of water, add 0.75 mL of 0.1 mol/L hydrochloric acid TS, and adjust to pH 8.5 with 0.1 mol/L sodium hydroxide TS. To this solution add 2 mL of a penicillinase solution prepared by dissolving penicillinase, equivalent to 513,000 Levy units, in 25 mL of water and neutralizing with dilute sodium hydroxide TS until a pale red color appears with 1 drop of a solution of phenolphthalein in ethanol (95) (1 in 1000) as indicator, and allow to stand at 25°C for 5 minutes. Titrate this solution with 0.1 mol/L sodium hydroxide VS until the solution reaches to pH 8.5 (potentiometric titration). Use the water freshly boiled and cooled.

Each mL of 0.1 mol/L sodium hydroxide VS = 36.240 mg of $C_{14}H_{15}N_2NaO_4S_2$

Thiodiglycol S(CH₂CH₂OH)₂ [β-Thiodiglycol for amino acid autoanalysis] Colorless or pale yellow, clear liquid.

Specific gravity d_{20}^{20} : 1.180 – 1.190 Water: not more than 0.7%.

Thioglycolate medium I for sterility test See the Sterility Test under the General Tests, Processes and Apparatus.

Thioglycolate medium II for sterility test See the Sterility Test under the General Tests, Processes and Apparatus.

Thioglycolic acid See mercapto acetic acid.

Thionyl chloride SOCl₂ [K 8148: 1961, Special class]

Thiopental for assay $C_{11}H_{18}N_2O_2S$ Dissolve 10 g of Thiopental Sodium in 300 mL of water. To this solution add slowly 50 mL of dilute hydrochloric acid with stirring. Take the produced crystals by filtration, wash with water until the filtrate indicates no reaction to chloride, and air-dry. Add diluted ethanol (99.5) (3 in 5), dissolve by heating in a water bath, allow to stand, and take the produced crystals by filtration. Air-dry the crystals in air, and dry again at $105^{\circ}C$ for 4 hours. White, odorless crystals.

Melting point: 159 - 162°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of thiopental for assay in dehydrated ethanol: the solution is clear and light yellow.

(2) Related substances—Dissolve 0.050 g of thiopental for assay in 15 mL of acetonitrile, add water to make 50 mL, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add the mobile phase in Purity (4) under Thiopental Sodium to make exactly 200 mL, and use

this solution as the standard solution. Proceed as directed in the Purity (4) under Thiopental Sodium.

Loss on drying: not more than 0.20% (1 g, 105 °C, 3 hours).

Content: not less than 99.0%. Assay—Weigh accurately about 0.35 g of thiopental for assay, previously dried, dissolve in 5 mL of dehydrated ethanol and 50 mL of chloroform, and titrate with 0.1 mol/L potassium hydroxide-ethanol VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L potassium hydroxide-ethanol VS = 24.234 mg of $C_{11}H_{18}N_2O_2S$

Thiosemicarbazide $H_2NCSNHNH_2$ [K 8632, Special class]

Thiourea H₂NCSNH₂ [K 8635, Special class]

Thiourea TS Dissolve 10 g of thiourea in water to make 100 mL.

L-Threonine $C_4H_9NO_3$ [Same as the namesake monograph]

Threoprocaterol hydrochloride $C_{16}H_{22}N_2O_3$.HCl To procaterol hydrochloride add 10 volumes of 3 mol/L hydrochloric acid TS, heat, and reflux for 3 hours. After cooling, neutralize (pH 8.5) with sodium hydroxide TS, and collect the crystals produced. Suspend the crystals in water, dissolve by acidifying the solution at pH 1 to 2 with addition of hydrochloric acid, neutralize (pH 8.5) by adding sodium hydroxide TS, and separate the crystals produced. Suspend the crystals in 2-propanol, and acidify the solution at pH 1 to 2 by adding hydrochloric acid. The crystals are dissolved and reproduced. Collect the crystals, dry at about 60°C while passing air. White to pale yellowish white, odorless crystals or crystalline powder.

Melting point: about 207°C (with decomposition).

Purity—Dissolve 0.1 g of threoprocaterol hydrochloride in 100 mL of diluted methanol (1 in 2), and use this solution as the sample solution. Perform the test with $2 \mu L$ of the sample solution as directed under the Liquid Chromatography according to the operating conditions in the Purity (3) under Procaterol Hydrochloride. Measure each peak area by the automatic integration method, and calculate the amount of threoprocaterol by the area percentage method: it shows the purity of not less than 95.0%. Adjust the detection sensitivity so that the peak height of threoprocaterol obtained from $2 \mu L$ of the solution prepared by diluting 5.0 mL of the sample solution with diluted methanol (1 in 2) to make 100 mL, is 5 to 10% of the full scale, and the time span of measurement is about twice as long as the retention time of threoprocaterol after the peak of solvent.

Thrombin [Same as the namesake monograph in Part II]

Thymol CH₃C₆H₃(OH)CH(CH₃)₂ [Same as the name-sake monograph in Part II]

Thymol blue C₂₇H₃₀O₅S [K 8643, Special class]

Thymol blue-N,N-dimethylformamide TS Dissolve 0.1 g of thymol blue in 100 mL of N,N-dimethylformamide.

Thymol blue-dioxane TS Dissolve 0.05 g of thymol blue in 100 mL of 1,4-dioxane, and filter if necessary. Prepare before use.

Thymol blue TS Dissolve 0.1 g of thymol blue in 100 mL of ethanol (95), and filter if necessary.

Thymol blue TS, dilute Dissolve 0.05 g of thymol blue in 100 mL of ethanol (99.5), and filter if necessary. Prepare before use.

Thymol for assay [Same as the monograph Thymol in Part II. It contains not less than 99.0% of thymol $(C_{10}H_{14}O)$.]

Thymolphthalein C₂₈H₃₀O₄ [K 8642, Special class]

Thymolphthalein TS Dissolve 0.1 g of thymolphthalein in 100 mL of ethanol (95), and filter if necessary.

Tin Sn [K 8580, Special class]

Tin for thermal analysis Sn [K 8580 (Tin). Content: not less than 99.99%]

Tin (II) chloride dihydrate SnCl₂.2H₂O [K 8136, Special class]

Tin (II) chloride-sulfuric acid TS Dissolve 10 g of tin (II) chloride dihydrate in diluted sulfuric acid (3 in 200) to make 100 mL.

Tin (II) chloride TS Dissolve 1.5 g of Tin (II) chloride dihydrate in 10 mL of water containing a small amount of hydrochloric acid. Preserve in glass-stoppered bottles in which a fragment of tin has been placed. Use within 1 month.

Tin (II) chloride TS, acidic Dissolve 8 g of Tin (II) chloride dihydrate in 500 mL of hydrochloric acid. Preserve in glass-stoppered bottles. Use within 3 months.

Titanium dioxide See titanium (IV) oxide.

Titanium dioxide TS See titanium (IV) oxide TS.

Titanium (III) chloride TiCl₃ [K 8401, Titanium trichloride (III) solution, First class] Store in light-resistant, glass-stoppered containers.

Titanium (III) chloride-sulfuric acid TS Mix carefully 20 mL of titanium (III) chloride TS and 13 mL of sulfuric acid, add carefully hydrogen peroxide (30) in small portions until a yellow color develops, and heat until white fumes evolve. After cooling, add water, heat again in the same manner, repeat this procedure until the solution is colorless, and add water to make 100 mL.

Titanium (III) chloride TS To titanium (III) chloride add dilute hydrochloric acid to obtain a solution containing 15 g/L of titanium (III) chloride (TiCl₃). Prepare before use.

Content: 14.0 – 16.0 g/L. Assay—Weigh accurately a portion of the sample, equivalent to about 0.8 g of titanium (III) chloride (TiCl₃), add 200 mL of water and 5 mL of a hydrochloric acid solution (2 in 3), and titrate with 0.1 mol/L ferric ammonium sulfate VS under carbon dioxide until a slight red color develops in the solution (indicator: 5 mL of ammonium thiocyanate TS).

Each mL of 0.1 mol/L ferric ammonium sulfate VS = 15.424 mg of TiCl₃

Titanium (IV) oxide TiO₂ [K 8703, Special class]

Titanium (IV) oxide TS To 100 mL of sulfuric acid add 0.1 g of titanium (IV) oxide, and dissolve by gradually heating on a flame with occasional gentle shaking.

Titanium trichloride See titanium (III) chloride.

Titanium trichloride-sulfuric acid TS See titanium (III) chloride-sulfuric acid TS.

Titanium trichloride TS See titanium (III) chloride TS.

Titanium yellow $C_{28}H_{19}N_5Na_2O_6S_4$ [K 8639, Special class]

 $\begin{array}{ccc} \textbf{Tocopherol} & C_{29}H_{50}O_2 & [\text{Same as the namesake monograph}] \end{array}$

Tocopherol acetate $C_{31}H_{52}O_3$ [Same as the namesake monograph]

Tocopherol calcium succinate $C_{66}H_{106}CaO_{10}$ [Same as the namesake monograph]

Tocopherol succinate $C_{33}H_{54}O_5$ Wet 0.5 g of tocopherol succinate with 5 mL of acetic acid (100), add 10 mL of toluene, and warm at 70°C for 30 minutes with occasional shaking. After cooling, add 30 mL of water, shake thoroughly, and allow to stand. Remove the water layer, wash the toluene layer with several 30-mL portions of water until the washings become neutral, and allow to stand. Shake the toluene extract with 3 g of anhydrous sodium sulfate, decant the toluene layer, distil the toluene under reduced pressure, and obtain a light yellow, viscous liquid. When preserved at room temperature for a long time, it becomes a pale yellowish solid.

Absorbance $E_{1 \text{ cm}}^{1\%}$ (286 nm): 38.0 – 42.0 (0.01 g, chloroform, 100 mL).

 $\begin{tabular}{lll} \textbf{Tolbutamide} & $C_{12}H_{18}N_2O_3S$ & [Same \ as \ the \ namesake \\ monograph] \end{tabular}$

Toluene C₆H₅CH₃ [K 8680, Special class]

 $o ext{-}Toluene$ sulfonamide $C_7H_9NO_2S$ Colorless crystals or white crystalline powder. Soluble in ethanol (95), and sparingly soluble in water.

Melting point: 157 – 160°C

Purity p-Toluene sulfonamide—Use a solution of otoluene sulfonamide in ethyl acetate (1 in 5000) as the sample solution. Perform the test with $10~\mu L$ of the sample solution as directed under the Gas Chromatography according to the operating conditions in the Purity (6) under Saccharin Sodium: any peak other than the peak of o-toluene sulfonamide does not appear. Adjust the flow rate so that the retention time of o-toluene sulfonamide is about 10 minutes, and adjust the detection sensitivity so that the peak height of o-toluene sulfonamide obtained from $10~\mu L$ of the sample solution is about 50% of the full scale. Time span of measurement is about twice as long as the retention time of o-toluene sulfonamide after the solvent peak.

Water: not more than 0.5% (4 g, use 25 mL of methanol for Karl Fischer method and 5 mL of pyridine for Karl Fischer method).

Content: not less than 98.5%, calculated on the anhydrous basis. Assay—Weigh accurately about 0.025 g of o-toluene sulfonamide, and perform the test as directed under the Nitrogen Determination.