Melting point: 87.5 - 90°C

Hydroxylamine perchlorate-dehydrated ethanol TS See hydroxylamine perchlorate-ethanol (99.5) TS.

Hydroxylamine perchlorate-ethanol (99.5) TS Dilute 2.99 mL of hydroxylamine perchlorate TS with ethanol (99.5) to make 100 mL.

Storage—Preserve in tight containers, in a cold place.

Hydroxylamine perchlorate TS An ethanol (95) solution which contains 13.4% of hydroxylamine perchlorate.

Storage—Preserve in tight containers, in a cold place.

Hydroxylamine TS Dissolve 10 g of hydroxylammonium chloride in 20 mL of water, and add ethanol (95) to make 200 mL. To this solution add, with stirring, 150 mL of 0.5 mol/L potassium hydroxide-ethanol VS, and filter. Prepare before use.

Hydroxylamine TS, alkaline Mix equal volumes of a solution of hydroxylammonium chloride in methanol (7 in 100) and a solution of sodium hydroxide in methanol (3 in 25), and filter. Prepare before use.

Hydroxylammine hydrochloride TS, pH 3.1 See hydroxylammonium chloride TS, pH 3.1.

Hydroxylammonium chloride $NH_2OH.HCl$ [K 8201, Special class]

Hydroxylammonium chloride-iron (III) chloride TS Acidify 100 mL of a solution of iron (III) chloride hexahydrate in ethanol (95) (1 in 200) with hydrochloric acid, and dissolve 1 g of hydroxylammonium chloride in the solution.

Hydroxylammonium chloride TS Dissolve 20 g of hydroxylammonium chloride in water to make 65 mL, transfer it to a separator, add 2 to 3 drops of thymol blue TS, then add ammonia solution (28) until the solution exhibits a yellow color. Shake well after adding 10 mL of a solution of sodium *N,N*-diethyldithiocarbamate trihydrate (1 in 25), allow to stand for 5 minutes, and extract this solution with 10 to 15 mL portions of chloroform. Repeat the extraction until 5 mL of the extract does not exhibit a yellow color, upon adding 5 drops of a solution of copper (II) sulfate pentahydrate (1 in 100) and shaking it. Add 1 to 2 drops of thymol blue TS, add dropwise dilute hydrochloric acid to this aqueous solution until it exhibits a red color, then add water to make 100 mL.

Hydroxylammonium chloride TS, pH 3.1 Dissolve 6.9 g of hydroxylammonium chloride in 80 mL of water, adjust the pH to 3.1 by adding dilute sodium hydroxide TS, and add water to make 100 mL.

Hydroxylammonium chloride-ethanol TS Dissolve 34.8 g of hydroxylammonium chloride in water to make 100 mL, and use this solution as Solution A. Dissolve 10.3 g of sodium acetate trihydrate and 86.5 g of sodium hydroxide in water to make 1000 mL, and use this solution as Solution B. Mix 1 volume of Solution A, 1 volume of Solution B and 4 volumes of ethanol (95).

4-Hydroxy-3-methoxybenzyl nonylic acid amide $C_{17}H_{27}NO_3$ A white crystalline powder, having a faint, characteristic odor.

Purity Related substances—Dissolve 0.01 g of 4-hydroxy-3-methoxybenzyl nonylic acid amide in 50 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 20 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the operating conditions in the Component determination under Capsicum: the total area of the peaks other than 4-hydroxy-3-methoxybenzyl nonylic acid amide from the sample solution is not larger than the peak area of 4-hydroxy-3-methoxybenzyl nonylic acid amide from the standard solution.

***N*-(3-Hydroxyphenyl)acetamide** $C_8H_6NO_2$ White to pale yellowish white crystals. It is freely soluble in ethanol (95), and sparingly soluble in water.

Melting point: 146 - 149°C

Purity (1) Clarity and color of solution—Dissolve 0.5 g of *N*-(3-hydroxyphenyl)acetamide in 50 mL of water: the solution is clear and colorless.

(2) Related substances—Dissolve 0.1 g of *N*-(3-hydroxyphenyl)acetamide in 1000 mL of water. Pipet 10 mL of this solution, add 6.5 mL of acetonitrile and water to make exactly 50 mL, and use this solution as the sample solution. Perform the test with 10 μL of the sample solution as directed in the Assay under Aspoxicillin: any peak other than those of *N*-(3-hydroxyphenyl)acetamide and the solvent does not appear.

3-(*p*-Hydroxyphenyl)propionic acid $C_9H_{10}O_3$

Description—White to light yellow-brown crystals or crystalline powder, having a faint, characteristic odor.

Content: not less than 99.0%. Assay—Weigh accurately about 0.2 g of 3-(*p*-hydroxyphenyl)propionic acid, previously dried (in vacuum, 60°C, 4 hours), dissolve in 5 mL of methanol, add 45 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 5 drops of bromothymol blue TS).

Each mL of 0.1 mol/L sodium hydroxide VS
= 16.617 mg of $C_9H_{10}O_3$

Hydroxypropylsilanized silica gel for liquid chromatography Prepared for liquid chromatography.

Hypophosphorus acid See phosphinic acid.

Hypoxanthine $C_5H_4N_4O$ White crystals or crystalline powder. Freely soluble in ammonia TS, sparingly soluble in dilute hydrochloric acid and in hot water, very slightly soluble in water, and practically insoluble in methanol.

Purity Related substances—Dissolve 5.0 mg of hypoxanthine in 100 mL of a solution of ammonia solution (28) in methanol (1 in 10) to make exactly 100 mL. Proceed with this solution as directed in the Purity (4) under Mercaptopurine: any spot other than the principal spot at the *Rf* value of about 0.2 does not appear.

Content: not less than 97.0% and not more than 103.0%. Assay—Weigh accurately about 0.15 g of hypoxanthine, previously dried at 105°C for 3 hours, and dissolve in phosphate buffer solution, pH 7.0, to make exactly 1000 mL. Pipet 10 mL of this solution, and dilute with phosphate buffer solution, pH 7.0, to make exactly 250 mL. Read the absorbance *A* of this solution at the wavelength of 250 nm as directed under the Ultraviolet-visible Spectrophotometry, using phosphate buffer solution, pH 7.0, as the blank solution.

$$\text{Amount (mg) of } C_5H_4N_4O = \frac{A}{779} \times 250{,}000$$

Ibuprofen $C_{13}H_{18}O_2$ [Same as the namesake monograph]

Imidazole $C_3H_4N_2$ White crystalline powder. Very soluble in water and in methanol.

Melting point: 89 - 92°C

Absorbance $E^{1\%}_{1\,cm}$ (313 nm): not more than 0.031 (8 g, water, 100 mL).

Imidazole for Karl Fischer method See the Water Determination under the General Tests, Processes and Apparatus.

Imidazole for thin-layer chromatography $C_3H_4N_2$ White, crystalline powder. Very soluble in water and in methanol, and freely soluble in ethyl acetate and in dichloromethane.

Melting point: 89 - 92°C

Purity Related substances—Dissolve 0.010 g of imidazole for thin-layer chromatography in exactly 20 mL of dichloromethane, and proceed with this solution as directed in the Purity (6) under Clotrimazole: any spot other than the principal spot does not appear.

Imidazole TS Dissolve 8.25 g of imidazole in 65 mL of water, adjust the pH to 6.80 with 5 mol/L hydrochloric acid TS, and add water to make exactly 1000 mL.

Iminodibenzyl $C_{14}H_{13}N$ White to light brown crystals or crystalline powder, having a slight, characteristic odor.

Melting point: 104 - 110°C

Purity (1) Clarity of solution—Dissolve 1.0 g of iminodibenzyl in 20 mL of methanol by heating on a water bath: the solution is clear.

(2) Related substances—Proceed as directed in the Purity (6) under Carbamazepine: any spot other than the principal spot at the *Rf* value of about 0.9 does not appear.

Nitrogen: 6.8 - 7.3% (Nitrogen Determination).

Imipramine hydrochloride $C_{19}H_{24}N_2.HCl$ [Same as the namesake monograph]

Indigo carmine $C_{16}H_8N_2Na_2O_8S_2$ [K 8092, Special class]

Indigo carmine TS Dissolve 0.20 g of indigo carmine in water to make 100 mL. Use within 60 days.

Indium for thermal analysis In Prepared for thermal analysis.

Content: not less than 99.99%.

2,3-Indolinedione $C_8H_5NO_2$ [K 8089, Special class]

Indometacin $C_{19}H_{16}ClNO_4$ [Same as the namesake monograph]

Iodine I [K 8920, Special class]

Iodine for assay I [Same as the monograph Iodine]

Iodine monobromide IBr Blackish brown crystals or masses.

It dissolves in water, in ethanol (95), in diethyl ether, in carbon disulfide and in acetic acid (100).

Melting point: 40°C

Storage—Preserve in light-resistant glass containers, in a cold place.

Iodine-starch TS To 100 mL of starch TS add 3 mL of dilute iodine TS.

Iodine trichloride ICl_3 [K 8403, Special class]

Iodine TS Dissolve 14 g of iodine in 100 mL of a solution of potassium iodide (2 in 5), add 1 mL of dilute hydrochloric acid, and dilute with water to make 1000 mL (0.05 mol/L).

Storage—Preserve in light-resistant containers.

Iodine TS, dilute To 1 volume of iodine TS add 4 volumes of water.

0.0002 mol/L Iodine TS Measure exactly 1 mL of 0.5 mol/L iodine TS, add water to make exactly 250 mL, pipet 10 mL of the solution, and add water to make exactly 100 mL. Prepare before use.

0.5 mol/L Iodine TS To 12.7 g of iodine and 25 g of potassium iodide add 10 mL of water, triturate, and add water to make 100 mL.

Iodoethane C_2H_5I [K 8911: 1981, Special class]

Iodomethane CH_3I [K 8919, Special class]

5-Iodouracil for liquid chromatography $C_4H_3IN_2O_2$ White, crystalline powder.

Melting point: about 275°C (with decomposition).

Purity—Dissolve 3 mg of 5-iodouracil for liquid chromatography in a mixture of diluted methanol (1 in 25) to make 10 mL. Perform the test with 10 μL of this solution as directed under the Liquid Chromatography, according to the operating conditions in the Purity under Idoxuridine Eye Drops. Measure each peak area by the automatic integration method over a time span of twice as long as the retention time of the principal peak, and calculate the amount of 5-iodouracil by the area percentage method: It shows the purity of not less than 98.5%.

Content: not less than 98.5%. Assay—Weigh accurately about 5 mg of 5-iodouracil for liquid chromatography, previously dried at 60°C for 3 hours under reduced pressure, dissolve in water to make exactly 250 mL. Perform the test with this solution as directed under the Ultraviolet-visible Spectrophotometry, and determine the absorbance *A* at the wavelength of maximum absorption at about 282 nm.

$$\text{Amount (mg) of 5-iodouracil } (C_4H_3IN_2O_2) = \frac{A}{265} \times 2500$$

Iotalamic acid for assay $C_{11}H_9I_3N_2O_4$ [Same as the monograph Iotalamic Acid]

Iron Fe Iron in the forms of strips, sheets, granules or wires. Fe: not less than 97.7%. It is attracted by a magnet.

Iron (III) chloride-acetic acid TS Dissolve 0.1 g of iron (III) chloride hexahydrate in diluted acetic acid (3 in 100) to make 100 mL.

Iron (III) chloride hexahydrate $FeCl_3.6H_2O$ [K 8142, Special class]

Iron (III) chloride-iodine TS Dissolve 5 g of iron (III) chloride hexahydrate and 2 g of iodine in a mixture of 50 mL of acetone and 50 mL of a solution of tartaric acid (1 in 5).

Iron (III) chloride-methanol TS Dissolve 1 g of iron (III) chloride hexahydrate in methanol to make 100 mL.

Iron (III) chloride-potassium hexacyanoferrate (III) TS Dissolve 0.1 g of potassium hexacyanoferrate (III) in 20 mL of iron (III) chloride TS. Prepare before use.

Iron (III) chloride-pyridine TS, anhydrous Heat gradually 1.7 g of iron (III) chloride hexahydrate by direct application of flame, melt, and solidify. After cooling, dissolve the residue in 100 mL of chloroform, add 8 mL of pyridine, and filter.

Iron (III) chloride TS Dissolve 9 g of iron (III) chloride hexahydrate in water to make 100 mL (1/3 mol/L).

Iron (III) chloride TS, acidic To 60 mL of acetic acid (100) add 5 mL of sulfuric acid and 1 mL of iron (III) chloride hexahydrate TS.

Iron (III) chloride TS, dilute Dilute 2 mL of iron (III) chloride hexahydrate TS with water to make 100 mL. Prepare before use.

Iron (III) nitrate enneahydrate $Fe(NO_3)_3.9H_2O$ [K 8559, Special class]

Iron (III) nitrate TS Dissolve 1 g of iron (III) nitrate enneahydrate in hydrochloric acid-potassium chloride buffer solution (pH 2.0) to make 300 mL.

Iron (III) perchlorate-ethanol TS Dissolve 0.8 g of iron (III) perchlorate hexahydrate in perchloric acid-ethanol TS to make 100 mL.

Storage—Preserve in tight containers, in a cold place.

Iron (III) perchlorate hexahydrate $Fe(ClO_4)_3.6H_2O$ Hygroscopic, light purple crystals, and a solution in ethanol (99.5) (1 in 125) is clear and orange in color.

Iron (III) sulfate *n*-hydrate $Fe_2(SO_4)_3.nH_2O$ [K 8981, Special class]

Iron (III) sulfate TS Dissolve 50 g of iron (III) sulfate *n*-hydrate in an excess of water, and add 200 mL of sulfuric acid and water to make 1000 mL.

Iron (II) sulfate heptahydrate $FeSO_4.7H_2O$ [K 8978, Special class]

Iron (II) sulfate TS Dissolve 8 g of iron (II) sulfate heptahydrate in 100 mL of freshly boiled and cooled water. Prepare before use.

Iron (II) sulfide FeS [K 8948, for hydrogen sulfide development]

Iron (II) tartrate TS Dissolve 1 g of iron (II) sulfate heptahydrate, 2 g of potassium sodium tartrate tetrahydrate and 0.1 g of sodium hydrogen sulfite in water to make 100 mL.

Iron (II) thiocyanate TS Add 3 mL of dilute sulfuric acid to 35 mL of water, and remove the dissolved oxygen by boiling the solution. Dissolve 1 g of iron (II) sulfate heptahydrate in this hot solution, cool, and then dissolve 0.5 g of potassium thiocyanate. When the solution is pale red in color, decolorize by adding reduced iron, separate the excess of reduced iron by decanting, and preserve the solution with protection from oxgen. Do not use a solution showing a pale red color.

Iron (II) trisodium pentacyanoamine TS To 1.0 g of sodium pentacyanonitrosylferrate (III) dihydrate add 3.2 mL of ammonia water, shake, stopper closely, and allow to stand in a refrigerator overnight. Add this solution to 10 mL of ethanol (99.5), filter a yellow colored precipitate by suction, wash with ether (99.5), dry, and preserve in a desiccator. Before using, dissolve in water to make a solution of 1.0 mg/mL, and store in a refrigerator. Use within 7 days after preparation.

Iron-phenol TS Dissolve 1.054 g of ammonium iron (II) sulfate hexahydrate in 20 mL of water, add 1 mL of sulfuric acid and 1 mL of hydrogen peroxide (30), heat until effervescence ceases, and dilute with water to make 50 mL. To 3 volumes of this solution contained in a volumetric flask add sulfuric acid, with cooling, to make 100 volumes, yielding the iron-sulfuric acid solution. Purify phenol by distillation, discarding the first 10% and the last 5%, and collect the distillate, with exclusion of moisture, in a dry, tared, glass-stoppered flask of about twice the volume of the phenol. Stopper the flask, solidify the phenol in an ice bath, breaking the top crust with a glass rod to ensure complete crystallization, and after drying, weigh the flask. To the glass-stoppered flask add 1.13 times the mass of phenol of the iron sulfuric acid solution, insert the stopper in the flask, and allow to stand, without cooling but with occasional shaking, until the phenol is liquefied, then shake the mixture vigorously. Allow to stand in a dark place for 16 to 24 hours. To the mixture add diluted sulfuric acid (10 in 21) equivalent to 23.5% of its mass, mix well, transfer to dry glass-stoppered bottles, and preserve in a dark place, with protection from atmospheric moisture. Use within 6 months.

Iron-phenol TS, dilute To 10 mL of iron-phenol TS add 4.5 mL of water. Prepare before use.

Iron powder Fe [K 8262: 1980, Reduced iron, Special class]

Isatin See 2,3-indolinedione.

Isoamyl acetate See 3-methylbutyl acetate.

Isoamyl alcohol See 3-methyl-1-butanol.

Isoamyl benzoate $C_{12}H_{16}O_2$

Specific gravity d_4^{15}: 0.993

Boiling point: 260 – 262°C

Isoamyl parahydroxybenzoate $C_{12}H_{16}O_3$ White crystalline powder, having a faint characteristic odor.

It is very soluble in acetonitrile, in ethanol (95), in acetone and in diethyl ether, and practically insoluble in water.

Melting point: 62 – 64°C

Isobutanol See 2-methyl-1-propanol.

Isobutyl parahydroxybenzoate $C_{11}H_{14}O_3$ Colorless crystals or white crystalline powder. Odorless. Freely soluble in ethanol (95), in acetone and in diethyl ether, and practically insoluble in water.

Melting point: 75 – 77°C

Residue on ignition: not more than 0.1%.

Content: not less than 98.0%. Assay—Proceed as directed in Assay under Ethyl Parahydroxybenzoate.

Each mL of 1 mol/L sodium hydroxide VS
= 194.23 mg of $C_{11}H_{14}O_3$

Isobutyl salicylate $C_{11}H_{14}O_3$ Colorless, clear liquid, having a characteristic odor.

Refractive index n_D^{20}: 1.506 - 1.511

Specific gravity d_4^{20}: 1.068 - 1.073

Boiling point: 260 - 262°C

Purity—Perform the test with 1 μL of isobutyl salicylate as directed under the Gas Chromatography according to the following conditions. Measure each peak area by the automatic integration method, and calculate the amount of isobutyl salicylate by the area percentage method: It shows the purity of not less than 97.0%.

Operating conditions

Detector: A thermal conductivity detector.

Column: A column about 3 mm in inside diameter and about 2 m in length, packed with siliceous earth for gas chromatography, 180 to 250 μm in particle diameter, coated with polythylene glycol 20 M for gas chromatography at the ratio of 10%.

Column temperature: A constant temperature of about 220°C.

Carrier gas: Helium

Flow rate: About 20 mL per minute.

Detection sensitivity: Adjust the detection sensitivity so that the peak height of isobutyl salicylate obtained from 1 μL of the sample solution is about 60% to 80% of the full scale.

Time span of measurement: About 3 times as long as the retention time of isobutyl salicylate after the solvent peak.

Isoniazid for assay $C_6H_7N_3O$ [Same as the monograph Isoniazid. When dried, it contains not less than 99.0% of isoniazid ($C_6H_7N_3O$).]

Isoniazid TS Dissolve 0.1 g of isoniazid for assay in a mixture of 50 mL of methanol and 0.12 mL of hydrochloric acid, and add methanol to make 200 mL.

Isonicotinic acid White, crystals or powder.

Melting point: about 315°C (decomposition).

Isonicotinic acid amide $C_6H_6N_2O$ White, crystals or crystalline powder.

Melting point: 155 - 158°C

Purity Clarity of solution—Dissolve 1.0 g of the substance to be tested in 20 mL of methanol: the solution is clear.

Content: not less than 99.0%. Assay—Weigh accurately about 0.3 g of isonicotinic acid amide, previously dried, and dissolve in 20 mL of acetic acid (100) by heating. After cooling, add 100 mL of benzene, and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from purple to blue-green (indicator: 3 drops of crystal violet TS). Perform a blank determination and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 11.213 mg of $C_6H_6N_2O$

Isooctane See octane, iso.

Isopromethazine hydrochloride for thin-layer chromatography $C_{17}H_{20}N_2S.HCl$ White, odorless, crystalline powder. Freely soluble in water, in ethanol (95) and in chloroform, and practically insoluble in diethyl ether.

Melting point: 193 - 197°C

Purity Related substances—Dissolve 5.0 mg of isopromethazine hydrochloride for thin-layer chromatography in exactly 25 mL of ethanol, and perform the test with this solution as directed in the Purity (3) under Promethazine Hydrochloride: any spot other than the principal spot at the *Rf* value of about 0.65 does not appear.

Isopropanol See 2-propanol.

Isopropanol for liquid chromatography See 2-propanol for liquid chromatography.

Isopropylamine See propylamine, iso.

Isopropylamine-ethanol TS To 20 mL of isopropylamine add ethanol (99.5) to make 100 mL. Prepare before use.

Isopropylether See propylether, iso.

Isopropyl iodide for assay C_3H_7I Colorless, clear liquid. On exposure to light it liberates iodine and becomes brown. Miscible with ethanol (95), with diethyl ether and with petroleum benzin, and not miscible with water. Use the distillate obtained between 89.0°C and 89.5°C.

Specific gravity d_4^{20}: 1.700 - 1.710

Purity—Perform the test with 1 μL of isopropyl iodide for assay as directed under the Gas Chromatography according to the operating conditions in the Assay under Hydroxypropylmethylcellulose 2208. Measure each peak area by the automatic integration method, and calculate the amount of isopropyl iodide by the area percentage method: It shows the purity of not less than 99.8%. Adjust the detection sensitivity so that the peak height of isopropyl iodide from 1 μL of isopropyl iodide for assay is about 80% of the full scale.

Content: not less than 98.0%. Assay—Transfer 10 mL of ethanol (95) into a brown volumetric flask, weigh accurately, add 1 mL of isopropyl iodide for assay, and weigh accurately again. Add ethanol (95) to make exactly 100 mL, pipet 20 mL of this solution into the second brown volumetric flask, add exactly 50 mL of 0.1 mol/L silver nitrate VS and then 2 mL of nitric acid, stopper, shake occasionally for 2 hours in a dark place, and allow to stand overnight in a dark place. Shake occasionally for 2 hours, add water to make exactly 100 mL, and filter through dry filter paper. Discard the first 20 mL of the filtrate, pipet the next 50 mL, and titrate the excess silver nitrate with 0.1 mol/L ammonium thiocyanate VS (indicator: 2 mL of ammonium iron (III) sulfate TS). Perform a blank determination in the same manner.

Each mL of 0.1 mol/L silver nitrate VS
= 16.999 mg of C_3H_7I

Isopropyl myristate $C_{17}H_{34}O_2$ Colorless, clear, oily liquid, and odorless. Congeals at about 5°C. Soluble in 90% alcohol, miscible with many organic solvents and with solid oils, and insoluble in water, in glycerin and in propylene glycol.

Refractive index n_D^{20}: 1.432 - 1.436

Specific gravity d_{20}^{20}: 0.846 - 0.854

Saponification value: 202 - 212

Acid value: not more than 1.

Iodine value: not more than 1.

Residue on ignition: not more than 0.1% (1 g).

Isopropyl myristate for sterility test $C_{17}H_{34}O_2$ Transfer 100 mL of isopropyl myristate into a centrifuge tube, add 100 mL of twice-distilled water, and shake vigorously