4. REAGENTS

Additional information for reagents that can only be fully identified by a trademark or whose availability is limited may be found in the KNOWLEDGE database on the EDQM website. This information is given only to make it easier to obtain such reagents and this does not suggest in any way that the mentioned suppliers are especially recommended or certified by the European Pharmacopoeia Commission or the Council of Europe. It is therefore acceptable to use reagents from another source provided that they comply with the standards of the Pharmacopoeia.

4.1. REAGENTS, STANDARD

4.1.1. REAGENTS

Acacia. 1000100. See Acacia (0307).

Acacia solution. 1000101. Dissolve 100 g of acacia R in 1000 ml of water R. Stir with a mechanical stirrer for 2 h. Centrifuge at about 2000 g for 30 min to obtain a clear solution. Storage: in polyethylene containers of about 250 ml capacity at 0 °C to -20 °C.


Acetoldehyde ammonia trimer trihydrate. C,H,N=O, . (M, 183.3). 1133500. [58052-80-5]. 2,4,6-Trimethylhexahydro-1,3,5-triazine trihydrate. mp: 95 °C to 97 °C.

Acetic acid, anhydrous. C,H,O,. (M, 60.1). 1000300. [64-19-7]. Content: minimum 99.6 per cent m/m of C,H,O,. A colourless liquid or white or almost white, shining, femo-like crystals, miscible with or very soluble in water, in alcohol, in glycerol (85 per cent), and in most fatty and essential oils.

Acetic acid, glacial. C,H,O,. (0590) See Acetic acid, glacial (0590).

Acetic acid, glacial (0590). See Acetic acid, glacial (0590).

Acetic acid, dilute. 1000401. Dilute 30 g of glacial acetic acid R to 100 ml with water R.

Acetic acid, dilute. 1000402. Content: 290 g/l to 310 g/l of C,H,O,. (M, 60.1). Dilute 30 g of glacial acetic acid R to 100 ml with water R.

Acetic anhydride. C,H,O,. (M, 102.1). 1000500. [108-24-7]. Content: minimum 97.0 per cent m/m of C,H,O,. A clear, colourless liquid. bp: 136 °C to 142 °C.

Assay. Dissolve 2.00 g in 50.0 ml of 1 M sodium hydroxide in a ground-glass-stoppered flask and boil under a reflux condenser for 1 h. Titrinate with 1 M hydrochloric acid, using 0.5 ml of phenolphthalein solution R as indicator. Calculate the number of millilitres of 1 M sodium hydroxide required for 1 g (n1). Dissolve 2.00 g in 20 ml of cyclohexane R in a ground-glass-stoppered flask, cool in ice and add a cold mixture of 10 ml of anthine R and 20 ml of cyclohexane R. Boil the mixture under a reflux condenser for 1 h, add 50.0 ml of 1 M sodium hydroxide and shake vigorously. Titrinate with
4.1.1. Reagents

1 M hydrochloric acid, using 0.5 ml of phenolphthalein solution R as indicator. Calculate the number of millilitres of 1 M sodium hydroxide required for 1 g (n1). Calculate the percentage of C,H,O from the expression:

\[
10.2 \times (n_1 - n_2)
\]

**Acetic anhydride solution R1. 1000501.**

Dissolve 25.0 ml of acetic anhydride R in anhydrous pyridine R and dilute to 100.0 ml with the same solvent. **Storage:** protected from light and air.

**Acetic anhydride - sulphuric acid solution. 1000502.** Carefully mix 5 ml of acetic anhydride R with 5 ml of sulphuric acid R. Add dropwise and with cooling to 50 ml of ethanol R. Prepare immediately before use.

**Acetone. 1000600. [67-64-1].** See Acetone (10872).

**Acetonitrile.** C3H3N. (M, 41.05). 1000700. [75-05-8]. Methyl cyanide. Ethanimine.

A clear, colourless liquid, miscible with water, with acetone cyanide. Ethanenitrile.

\[d_20^0\]: about 0.78.

\[n_2^0\]: about 1.344.

A 100 g/l solution is neutral to litmus paper.

**Distillation range (2.2.11).** Not less than 95 per cent distils between 80 °C and 82 °C.

Acetonitrile used in spectrophotometry complies with the following additional requirement.

**Minimum transmittance (2.2.25):** 98 per cent from 255 nm to 420 nm, using water R as compensation liquid.

**Acetonitrile for chromatography. 1000701.** See Acetonitrile R.

Acetonitrile used in chromatography complies with the following additional requirements.

**Minimum transmittance (2.2.25):** 98 per cent from 240 nm, using water R as compensation liquid.

**Minimum purity (2.2.28):** 99.8 per cent.

**Acetonitrile R1. 1000702.**

Complies with the requirements prescribed for acetonitrile R and with the following additional requirements.

**Content: minimum 99.9 per cent of C3H3N.**

**Absorbance (2.2.25).** The absorbance at 200 nm using water R as the compensation liquid is not more than 0.10.

**Acetoxyvalerenic acid.** C17H24O4. (M, 292.4). 1165800. [81397-67-3]. (2E)-3-[[1RS,4S,5R,7aR]-1-(Acetoxyl)-3,7-dimethyl-2,4,5,6,7,7a-hexahydro-1H-inden-4-yl]-2-methylprop-2-enoic acid.

Colourless or pale yellow viscous oil.

**Absorbance (2.2.25):** absorption maximum at about 216 nm, determined in methanol R.

**Acetylamide.** C5H8O2. (M, 101.1). 1102600. [5977-14-0]. 3-Oxobutanamide.

mp: 53 °C to 56 °C.

**Acetylacetone.** C5H8O2. (M., 100.1). 1000900. [123-54-6]. 2,4-Pentanedione.

A colourless or slightly yellow, easily flammable liquid, freely soluble in water, miscible with acetone, with alcohol and with glacial acetic acid.

\[n_2^0\]: 1.452 to 1.453.

bp: 138 °C to 140 °C.

**Acetylacetone reagent R1. 1000901.**

To 100 ml of ammonium acetate solution R add 0.2 ml of acetylacetone R.

**N-Acetyl-β-caprolactam.** C7H16ClNO2. (M, 155.2). 1102700. [1888-91-1]. N-Acetylhexane-6-lactam.

Colourless liquid, miscible with ethanol.

\[d_20\]: about 1.100.

\[n_2^0\]: about 1.489.

bp: about 135 °C.

**Acetyl chloride.** C2H3ClO. (M, 78.5). 1000800. [75-36-5].

A clear, colourless liquid, flammable, decomposes in contact with water and with alcohol, miscible with ethylene chloride.

\[d_20\]: about 1.10.

**Distillation range (2.2.11).** Not less than 95 per cent distils between 49 °C and 53 °C.

**Acetylcibichloride.** C16H18ClNO2. (M, 181.7). 1001000. [60-31-1].

A crystalline powder, very soluble in cold water and in alcohol; it decomposes in hot water and in alkalis.

**Storage:** at –20 °C.


White or almost white powder, insoluble in water, soluble in alcohol; it decomposes in hot water and in alkalis.

**Storage:** at –20 °C.

**Acetyleugenol used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Clove oil (1091) using the substance to be examined as the test solution.

The area of the principal peak is not less than 98.0 per cent of the total area of the peaks.

**N-Acetylglucosamine.** C8H15NO6. (M, 221.2). 1133600. [7512-17-6]. 2-(Acetamido)-2-deoxy-D-glucopyranose.

mp: about 202 °C.


White or almost white powder, insoluble in water, soluble in acetone, in anhydrous ethanol and in methanol.

mp: 271 °C to 274 °C.

**Acetyl-11-keto-β-boswellic acid used in liquid chromatography complies with the following additional test.**

**Assay.** Liquid chromatography (2.2.29) as prescribed in the monograph on Indian frankincense (2310).

**Content:** minimum 90 per cent, calculated by the normalisation procedure.

See the information section on general monographs (cover pages)
**Acetylneuraminic acid.** C₇H₁₆N₃O₇S₃. (M₁, 309.3). 1001100.
[131-48-6]. O-Sialic acid.

White or almost white acicular crystals, soluble in water and in methanol, slightly soluble in ethanol, practically insoluble in acetone.

[n]D₂₀: about -36, determined on a 10 g/l solution.

mp: about 186 °C, with decomposition.

**Acetyltryptophan.** C₁₇H₁₇N₂O₆. (M₂, 246.3). 1102800.
[1218-34-4]. 2-Acetylamino-3-(indol-3-yl)propanoic acid.

A white or almost white powder or colourless crystals, slightly soluble in water. It dissolves in dilute solutions of alkali hydroxides.

Colour Index No. 42655.

[6104-58-1].

**Acetyltyrosine ethyl ester.** C₁₃H₁₉NO₄. (M₃, 269.3). 1001200.
[36546-50-6]. N-Acetyl-L-tyrosine ethyl ester monohydrate. Ethyl (S)-2-acetamido-3-(4-hydroxyphenyl)propionoate monohydrate.

A white or almost white, crystalline powder suitable for the assay of chymotrypsin.

[n]D₂₀: +21 to +25, determined on a 10 g/l solution in alcohol.

A₁ vs.: 60 to 68, determined at 278 nm in alcohol R.

Acetyltyrosine ethyl ester 0.2 M.

Dissolve 0.54 g of acetyltyrosine ethyl ester R in alcohol R and dilute to 10.0 ml with the same solvent.

**Acid blue 83.** C₈H₈N₃Na₂O₆S₂. (M₄, 826). 1012200.
[6104-59-2].

Colour Index No. 42660.

Brilliant blue R. Coomassie brilliant blue R 250.

Brown powder insoluble in cold water, slightly soluble in boiling water and in ethanol, soluble in sulphuric acid, glacial acetic acid and in dilute solutions of alkali hydroxides.

**Acid blue 90.** C₁₃H₁₇N₂O₅S₂. (M₅, 854). 1001300.
[6104-58-1].

Colour Index No. 42655.

Sodium [4-[(4-ethyl)[(4-ethyl)phenyl][4-ethyl]3-sulphonatobenzenyl]amino]phenyl)methylene[cyclo-hexa-2,5-dien-1-ylidine][ethyl]-O-sulphonatobenzoylammonium.

A dark brown powder, with a violet sheen and some particles having a metallic lustre, soluble in water and in methanol.

A₁ vs.: greater than 500, determined at 577 nm using a 0.01 g/l solution in buffer solution pH 7.0 and calculated with reference to the dried substance.

Loss on drying (2.2.32): maximum 5.0 per cent, determined on 0.500 g by drying in an oven at 105 °C.

**Acid blue 92.** C₁₉H₂₁N₃Na₂O₆S₂. (M₆, 696). 1001400.
[3861-73-2].

Colour Index No. 13390.

Coomassie blue. Anazolene sodium. Trisodium 8-hydroxy-4′- (phenylamino)azonaphthalene-3,5′,6-trisulphonate.

Dark blue crystals slightly soluble in alcohol, soluble in water, in acetone and in ethylene glycol monoethylether.

Acid blue 92 solution. 1001401.

Dissolve 0.5 g of acid blue 92 R in a mixture of 10 ml of glacial acetic acid R, 45 ml of alcohol R and 45 ml of water R.

**Acid blue 93.** C₂₀H₂₁N₃Na₂O₆S₃. (M₇, 800). 1134200.
[28983-56-4].

Colour Index No. 42780.

Methyl blue. Poirrier blue.

Light blue powder.

Colour change: pH 9.4 to pH 14.0.

Acid blue 93 solution. 1134201.

Dissolve 0.2 g of acid blue 93 R in water R and dilute to 100 ml with the same solvent.

**Acrylamide.** C₃H₅NO. (M₈, 71.1). 1001500.
[79-06-1].

Propenamide.

Colourless or white flakes or a white or almost white, crystalline powder, very soluble in water and in methanol, freely soluble in ethanol.

mp: about 84 °C.

30 per cent acrylamide/bisacrylamide (29:1) solution. 1001501.

Prepare a solution containing 290 g of acrylamide R and 10 g of methylenebisacrylamide R per litre of water R. Filter.

30 per cent acrylamide/bisacrylamide (36.5:1) solution. 1001502.

Prepare a solution containing 292 g of acrylamide R and 8 g of methylenebisacrylamide R per litre of water R. Filter.

**Acrylic acid.** C₅H₈O₂. (M₉, 72.1). 1133700.
[79-10-7].

Prop-2-enoic acid. Vinylformic acid.

Content: minimum 99 per cent of C₅H₈O₂.

It is stabilised with 0.02 per cent of hydroquinone monomethyl ether.

Corrosive liquid, miscible with water and alcohol. It polymerises readily in the presence of oxygen.

ρ₂₀: about 1.05.

n₂₀: about 1.421.

bp: about 141 °C.

mp: 12 °C to 15 °C.

**Acetoside.** C₁₉H₂₅O₅. (M₁₀, 624.6). 1145100.
[61276-17-3]. 2(3,4-Dihydroxyphenyl)ethyl 3-O(6-deoxy-a-L-mannopyranosyl)-4-O[(2E)-3-(3,4-dihydroxyphenyl)prop-2-enoyl]-ß-D-glucopyranoside.

Light yellowish powder, freely soluble in water and in methanol.

mp: about 140 °C, with decomposition.

Adenosine. C₁₀H₁₇N₅O₅. (M₁₁, 267.2). 1001600.
[58-61-7].

6-Amino-9-β-D-ribofuranosyl-9H-purine.

A white or almost white, crystalline powder, slightly soluble in water, practically insoluble in acetone and in alcohol. It dissolves in dilute solutions of acids.

mp: about 234 °C.

Adipic acid. C₇H₁₀O₄. (M₁₂, 146.1). 1095600.
[124-04-9].

Prisms, freely soluble in methanol, soluble in acetone, practically insoluble in light petroleum.

mp: about 152 °C.
4.1.1. Reagents

**Adrenalin.** C$_{18}$H$_{27}$NO$_3$. (M, 312.3). 1166000. [56-41-7].

A white or almost white crystalline powder.

**Adrenalinum hydrochloride.** C$_{18}$H$_{26}$ClNO$_3$. (M, 325.8). 1104800. [9048-46-8].

A white or almost white, slightly yellowish, amorphous powder.

**Agarose for chromatography.** 1002100.

Swollen beads 60 µm to 140 µm in diameter and presented as a 4 per cent suspension in water R. It is used in size-exclusion chromatography for the separation of proteins with relative molecular masses of 6 × 10$^4$ to 20 × 10$^6$ and of polysaccharides with relative molecular masses of 3 × 10$^3$ to 5 × 10$^6$.

**Agarose for chromatography, cross-linked R1.** 1001900. [65099-79-8].

Prepared for agarose by reaction with 2,3-dibromopropanol in strongly alkaline conditions. It occurs as swollen beads 60 µm to 140 µm in diameter and is presented as a 4 per cent suspension in water R. It is used in size-exclusion chromatography for the separation of proteins with relative molecular masses of 7 × 10$^4$ to 40 × 10$^6$ and of polysaccharides with relative molecular masses of 1 × 10$^3$ to 2 × 10$^6$.

**Agarose for electrophoresis.** 1002000. [9012-36-6].

A neutral, linear polysaccharide, the main component of which is derived from agar.

**Albunin, bovine.** 1002300. [9048-46-8].

Bovine serum albumin containing about 96 per cent of protein.

**Albumin solution, human.** 1002400. [9048-46-8].

See Human albumin solution (0255).
**Aldehyde dehydrogenase.** 1103000.
Enzyme obtained from baker’s yeast which oxidises acetaldehyde to acetic acid in the presence of nicotinamide-adenine dinucleotide, potassium salts and thiols, at pH 8.0.

**Aldehyde dehydrogenase solution.** 1103001.
Dissolve in water R a quantity of aldehyde dehydrogenase R, equivalent to 70 units and dilute to 10 ml with the same solvent. This solution is stable for 8 h at 4 °C.

**Aldrin.** C12H8Cl6. (M, 364.9). 1123100. [309-00-2].
bp: about 145 °C.
mp: about 104 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

**Aleuritic acid.** C16H32O5. (M, 304.4). 1095700. [533-87-9].

A white or almost white powder, greasy to the touch, soluble in methanol.

**Alizarin S.** C10H7NaO7S.H2O. (M, 360.3). 1002600. [130-22-3].
Schultz No. 1145.
Colour Index No. 58005.

Dissolve 65.0 g of aluminium chloride R in water R and dilute to 100 ml with the same solvent. Add 0.5 g of activated charcoal R, stir for 10 min, filter and add to the filtrate, with continuous stirring, sufficient of a 10 g/l solution of sodium hydroxide R (about 60 ml) to adjust the pH to about 1.5.

**Aluminium nitrate.** Al(NO3)3.9H2O. (M, 375.1). 1002800. [7784-27-2]. Aluminium nitrate nonahydrate.
Crystals, deliquescent, very soluble in water and alcohol, very slightly soluble in acetone.

Storage: in an airtight container.

**Aluminium oxide, anhydrous.** 1002900. [1344-28-1].
An aluminium oxide, consisting of γ-Al2O3, dehydrated and activated by heat treatment. Particle size 75 µm to 150 µm.

**Aluminium oxide, basic.** 1118300.
A basic grade of anhydrous aluminium oxide R suitable for column chromatography.

**Aluminium oxide, neutral.** Al2O3. (M, 102.0). 1118400.
See Aluminium oxide, hydrated (0311).

**Aluminium potassium sulphate.** 1003000. [7784-24-9].
See Alum (0006).

**Ameriacium-243 spiking solution.** 1167500.
Contains 50 Bq/l 243Pu and a 134 g/l solution of lanthanum chloride heptahydrate R in a 103 g/l solution of hydrochloric acid R.

**Amido black 10B.** C22H14N6Na2O9S2. (M, 117.0). 1003100. [1064-48-8].
Schultz No. 299.
Colour Index No. 20470.

A dark-brown to black powder, sparingly soluble in water, soluble in alcohol.

**Amido black 10B solution.** 1003101.
A 5 g/l solution of amido black 10B R in a mixture of 10 volumes of acetic acid R and 90 volumes of methanol R.

**Aminooazobenzene.** C9H7N3. (M, 197.2). 1003200. [60-09-3].
Colour Index No. 11000.
4-(Phenylazo)aniline.
Brownish-yellow, crystalline powder, hygroscopic, freely soluble in water and in alcohol.

Storage: in an airtight container.

Contains 50 Bq/l 243Pu and a 134 g/l solution of lanthanum chloride heptahydrate R in a 103 g/l solution of hydrochloric acid R.

**Aluminium chloride reagent.** 1002702.
Dissolve 2.0 g of aluminium chloride R in an airtight container.

**Aluminium chloride solution.** 1002701.
Dissolve 65.0 g of aluminium chloride R in water R and dilute to 100 ml with the same solvent. Add 0.5 g of activated charcoal R, stir for 10 min, filter and add to the
4-Aminobutanol. \( \text{C}_4\text{H}_11\text{NO} \). (mp: about 202 °C (decreases on rapid heating). slightly soluble in other solvents. Leaflets from methanol and ether, needles from water and

Storage: protected from light.

4-Aminobutanoic acid. \( \text{C}_4\text{H}_9\text{NO}_2 \). (mp: about 200 °C. White or almost white, crystalline powder. (2R)-4-Aminobutyric acid. GABA.

Storage: protected from light.

4-Aminobenzoic acid. \( \text{C}_6\text{H}_4\text{NO}_2 \). (mp: about 205 °C. Aminohippuric acid. 4-Amino-3-hydroxynaphthalene-1-sulphonic acid. 4-Amino-3-hydroxynaphthalene-1-sulphonic acid solution. 1112401. Mix 5.0 g of anhydrous sodium sulphite \( \text{R} \) with 94.3 g of sodium hydrogensulphite \( \text{R} \) and 0.7 g of anhydroxynaphthalenesulphonic acid \( \text{R} \). Dissolve 1.5 g of the mixture in water \( \text{R} \) and dilute to 10.0 ml with the same solvent. Prepare the solution daily.

cis-Aminoindanol. \( \text{C}_9\text{H}_9\text{NO} \). (M 149.2). 1168300. (1S,2R)-1-Amino-2,3-dihydro-1H-inden-2-ol. (−)-cis-1-Aminoindan-2-ol.

Content: minimum 98.0 per cent (sum of enantiomers, determined by gas chromatography). [(α)

Loss on drying (2.2.32): maximum 10.0 per cent, determined on 1.000 g.

Aminomethylalizarindiacetic acid. \( \text{C}_19\text{H}_{15}\text{NO}_8,2\text{H}_2\text{O} \). (mp: 118 °C to 122 °C. Aminomethylalizarindiacetic acid reagent. 1003701. Dissolve 3 g of phthalic acid \( \text{R} \) and 0.3 g of aminohippuric acid \( \text{R} \) in alcohol \( \text{R} \) and dilute to 100 ml with the same solvent.

Aminohydroxynaphthalenesulphonic acid. \( \text{C}_7\text{H}_6\text{NO}_5\text{S} \). (M 239.3). 1112400. [116-63-2]. 4-Amino-3-hydroxynaphthalene-1-sulphonic acid. White or grey needles, turning pink on exposure to light, especially when moist, practically insoluble in water and in alcohol, soluble in solutions of alkali hydroxides and in hot solutions of sodium metabisulphite.

Storage: protected from light.

Aminohydroxynaphthalenesulphonic acid solution. 1112401. Mix 5.0 g of anhydrous sodium sulphite \( \text{R} \) with 94.3 g of sodium hydrogensulphite \( \text{R} \) and 0.7 g of aminohydroxynaphthalenesulphonic acid \( \text{R} \). Dissolve 1.5 g of the mixture in water \( \text{R} \) and dilute to 10.0 ml with the same solvent. Prepare the solution daily.

cis-Aminoindanol. \( \text{C}_9\text{H}_9\text{NO} \). (M 149.2). 1168300. (1S,2R)-1-Amino-2,3-dihydro-1H-inden-2-ol. (−)-cis-1-Aminoindan-2-ol.

Content: minimum 98.0 per cent (sum of enantiomers, determined by gas chromatography). [(α)

Loss on drying (2.2.32): maximum 10.0 per cent, determined on 1.000 g.

Aminomethylalizarindiacetic acid reagent. 1003901. Solution I. Dissolve 0.36 g of cerous nitrate \( \text{R} \) in water \( \text{R} \) and dilute to 50 ml with the same solvent. Solution II. Suspended 0.7 g of aminomethylalizarindiacetic acid \( \text{R} \) in 50 ml of water \( \text{R} \). Dissolve with the aid of about 0.25 ml of concentrated ammonia \( \text{R} \), add 0.25 ml of glacial acetic acid \( \text{R} \) and dilute to 100 ml with water \( \text{R} \). Solution III. Dissolve 6 g of sodium acetate \( \text{R} \) in 50 ml of water \( \text{R} \), add 11.5 ml of glacial acetic acid \( \text{R} \) and dilute to 100 ml with water \( \text{R} \). To 33 ml of acetone \( \text{R} \) add 6.8 ml of solution III, 1.0 ml of solution II and 1.0 ml of solution I and dilute to 50 ml with water \( \text{R} \). Test for sensitivity. To 1.0 ml of fluoride standard solution (10 ppm F) \( \text{R} \) add 19.0 ml of water \( \text{R} \) and 5.0 ml of the aminomethylalizarindiacetic acid reagent. After 20 min, the solution assumes a blue colour.

Storage: use within 5 days.

Aminomethylalizarindiacetic acid solution. 1003902. Dissolve 0.192 g of aminomethylalizarindiacetic acid \( \text{R} \) in 6 ml of freshly prepared 1 M sodium hydroxide. Add 750 ml of water \( \text{R} \), 25 ml of succinate buffer solution \( \text{pH} 4.6 \text{R} \) and, dropwise, 0.5 M hydrochloric acid until
the colour changes from violet-red to yellow (pH 4.5 to 5). Add 100 ml of acetone R and dilute to 1000 ml with water R.

**4-Aminomethylbenzoic acid.** C₇H₈NO₂. (M, 151.2). 1167800. [56-91-7].


mp: about 160 °C.

A1 [35]: 690 to 720, determined at 233 nm using a 0.01 g/l solution in methanol R.

**6-Aminopenicillanic acid.** C₁₃H₁₇N₃O₂. (M, 216.3). 1162100. [551-16-6]. (25S,R,6R)-6-Amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

**Appearance:** white or almost white powder.

mp: about 205 °C, with decomposition.

**Aminophenazone.** C₁₃H₁₇N₃O. (M, 231.3). mp: about 205 °C, with decomposition.

**C₈H₉NO₂. (4-Aminomethylbenzoic acid.** C₆H₇NO. (M, 109.1). 1147500. [123-30-8]. 4-(Dimethylamino)-1,5-dimethyl-2-phenyl-1,2-dihydro-3H-pyrazol-3-one.

**Content:** minimum 99 per cent of C₃H₇NO₂.

**Storage:** mp: about 186 °C, with decomposition.

**Water, soluble in ethanol.**

A white or slightly coloured, crystalline powder, becoming colourless on exposure to air and light, sparingly soluble in water, soluble in alcohol.

mp: about 205 °C, with decomposition.

**βανιμο recordings** applied to all monographs and other texts

**Aminopolyether.** C₁₈H₃₆N₂O₆. (M, 376.5). 1112500. [23978-09-8]. 8,8-bis[2-(dimethylamino)ethyl]-8,8-dihydroxy-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[8.8.8]hexacosane.

mp: 70 °C to 73 °C.

**3-Aminopropanol.** C₃H₇NO. (M, 75.1). 1004400. [156-87-6]. 3-Aminopropan-1-ol. Propanolamine.

**Content:** minimum 99 per cent of C₃H₇NO₂.

A clear, colourless, viscous liquid.

[α]D₂₀: about 0.99.

nD₂₀: about 1.461.

mp: about 11 °C.

**3-Aminopropionic acid.** C₃H₇NO₂. (M, 89.1). 1004500. [107-95-9]. β-Alanine.

**Content:** minimum 99 per cent of C₃H₇NO₂.

A white or almost white, crystalline powder, freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone.

mp: about 200 °C, with decomposition.

**Aminopyrazolone.** C₃H₇NO. (M, 203.2). 1004600. [83-07-8]. 4-Amino-2,3-dimethyl-1-phenylpyrazolin-5-one. Light-yellow needles or powder, sparingly soluble in water, freely soluble in alcohol.

mp: about 108 °C.

**Aminopyrazolone solution.** 1004601. A 1 g/l solution in buffer solution pH 9.0 R.

**Ammonia, concentrated.** 1004700. See Concentrated ammonia solution (0877).

**Ammonia.** 1004701. **Content:** 170 g/l to 180 g/l of NH₃ (M, 17.03). Dilute 67 g of concentrated ammonia R to 100 ml with water R.

**Ammonia, dilute R1.** 1004702. Content: 100 g/l to 104 g/l of NH₃ (M, 17.03). Dilute 41 g of concentrated ammonia R to 100 ml with water R.

**Ammonia, dilute R2.** 1004703. Content: 33 g/l to 35 g/l of NH₃ (M, 17.03). Dilute 14 g of concentrated ammonia R to 100 ml with water R.

**Ammonia, dilute R3.** 1004704. Content: 1.6 g/l to 1.8 g/l of NH₃ (M, 17.03). Dilute 0.7 g of concentrated ammonia R to 100 ml with water R.

**Ammonia, dilute R4.** 1004706. Content: 8.4 g/l to 8.6 g/l of NH₃ (M, 17.03). Dilute 3.5 g of concentrated ammonia R to 100 ml with water R.

**Ammonia, lead-free.** 1004705. Complies with the requirements prescribed for dilute ammonia R1 and with the following additional test: to 20 ml of lead-free ammonia, add 1 ml of lead-free potassium cyanide solution R, dilute to 50 ml with water R and add 0.10 ml of sodium sulphide solution R. The solution is not more intensely coloured than a reference solution prepared without sodium sulphide.

**Ammonia, concentrated R1.** 1004800. **Content:** minimum 32.0 per cent m/m of NH₃ (M, 17.03). A clear, colourless liquid.

[α]D₂₀: 0.883 to 0.889.

**Assay.** Weigh accurately a ground-glass-stoppered flask containing 50.0 ml of 1 M hydrochloric acid. Introduce 2 ml of the concentrated ammonia and weigh again. Titrate the solution with 1 M sodium hydroxide, using 0.5 ml of methyl red mixed solution R as indicator.

1 ml of 1 M hydrochloric acid is equivalent to 17.03 mg of NH₃.
4.1.1. Reagents

**Storage:** protected from atmospheric carbon dioxide, at a temperature below 20 °C.

**Ammonium acetate.** C₂H₃NO₂ (M, 77.1). 1004900.

[631-61-8].

Colourless crystals, very deliquescent, very soluble in water and in alcohol.

**Storage:** in an airtight container.

**Ammonium acetate solution.** 1004901.

Dissolve 150 g of ammonium acetate R in water R. Add 3 ml of glacial acetic acid R and dilute to 1000 ml with water R.

**Storage:** use within 1 week.

**Ammonium and cerium nitrate.** (NH₄)₄Ce(NO₃)₆ (M, 548.2). 1005000. [16774-21-3].

A white or almost white, crystalline powder, or colourless crystals, soluble in water.

**Ammonium and cerium sulphate.** (NH₄)₄Ce(SO₄)₄.2H₂O. (M, 633). 1005100. [10378-47-9].

Deliquescent crystals or granules, very soluble in water, practically insoluble in alcohol.

**Ammonium carbonate.** CH₅N₂O₂. (M, 78.1). 1168400. [1111-78-0].

A white or almost white, crystalline powder or crystals, slowly soluble in water.

1m lo f 1 M hydrochloric acid: at a temperature below 20 °C.

**Ammonium carbonate solution.** 1005200.

A mixture of varying proportions of ammonium hydrogen carbonate (NH₄HCO₃, M, 79.1) and ammonium carbamate (NH₄COONH₂, M, 78.1).

A white or almost white translucent mass, slowly soluble in about 4 parts of water. It is decomposed by boiling water. Ammonium carbonate liberates not less than 30 per cent m/m of NH₃. (M, 17.03).

**Assay.** Dissolve 2.00 g in 25 ml of water R. Slowly add 50.0 ml of 1 M hydrochloric acid, titrate with 1 M sodium hydroxide, using 0.1 ml of methyl orange solution R as indicator.

1 ml of 1 M hydrochloric acid is equivalent to 17.03 mg of NH₃.

**Storage:** at a temperature below 20 °C.

**Ammonium carbonate solution.** 1005201.

A 158 g/l solution.

**Ammonium chloride.** 1005300. [12125-02-9].

See Ammonium chloride (0007).

**Ammonium chloride solution.** 1005301.

A 107 g/l solution.


A white or almost white, crystalline powder or colourless crystals, freely soluble in water, slightly soluble in alcohol.

**pH (2.2.3):** about 4.3 for a 22.6 g/l solution.

**Ammonium dihydrogen phosphate.** (NH₄)H₂PO₄. (M, 115.0). 1005400. [7722-76-1]. Monobasic ammonium phosphate.

A white or almost white, crystalline powder or colourless crystals, freely soluble in water.

**pH (2.2.3):** about 4.2 for a 23 g/l solution.

**Ammonium formate.** CH₂NO₂. (M, 63.1). 1112600. [540-69-2]. Deliquescent crystals or granules, very soluble in water, soluble in alcohol.

mp: 119 °C to 121 °C.

**Storage:** in an airtight container.

**Ammonium hexafluorogermanate (IV).** (NH₄)₆GeF₆. (M, 227.7). 1134000. [16962-47-3].

White or almost white crystals, freely soluble in water.

**Ammonium hydrogen carbonate.** NH₄HCO₃. (M, 79.1). 1005500. [1066-33-7].

**Content:** minimum 99 per cent of NH₄HCO₃.

**Ammonium molybdate.** (NH₄)₆Mo₇O₂₄.4H₂O. (M, 1236). 1105700. [12054-85-2].

Colourless or slightly yellow or greenish crystals, soluble in water, practically insoluble in alcohol.

**Ammonium molybdate reagent.** 1005701.

Mix, in the given order, 1 volume of a 25 g/l solution of ammonium molybdate R, 1 volume of a 100 g/l solution of ascorbic acid R and 1 volume of sulphuric acid R (294.5 g/l H₂SO₄). Add 2 volumes of water R.

**Storage:** use within 1 day.

**Ammonium molybdate reagent R1.** 1005706.

Mix 10 ml of a 60 g/l solution of disodium arsenate R, 50 ml of ammonium molybdate solution R, 90 ml of dilute sulphuric acid R and dilute to 200 ml in water R.

**Storage:** in amber flasks at 37 °C for 24 h.

**Ammonium molybdate reagent R2.** 1005708.

Dissolve 50 g of ammonium molybdate R in 600 ml of water R. To 250 ml of cold water R add 150 ml of sulphuric acid R and cool. Mix the 2 solutions together.

**Storage:** use within 1 day.

**Ammonium molybdate solution.** 1005702.

A 100 g/l solution.

**Ammonium molybdate solution R3.** 1005703.

Dissolve 5.0 g of ammonium molybdate R with heating in 30 ml of water R. Cool, adjust the pH to 7.0 with dilute ammonia R2 and dilute to 50 ml with water R.

**Ammonium molybdate solution R3.** 1005704.

Solution I. Dissolve 5 g of ammonium molybdate R in 20 ml of water R with heating.

Solution II. Mix 150 ml of alcohol R with 150 ml of water R. Add with cooling 100 ml of sulphuric acid R.

Immediately before use add 80 volumes of solution II to 20 volumes of solution I.

**Ammonium molybdate solution R4.** 1005705.

Dissolve 1.0 g of ammonium molybdate R in water R and dilute to 40 ml with the same solvent. Add 3 ml of hydrochloric acid R and 5 ml of perchloric acid R and dilute to 100 ml with acetone R.

**Storage:** protected from light; use within 1 month.

**Ammonium molybdate solution R5.** 1005707.

Dissolve 1.0 g of ammonium molybdate R in 40.0 ml of a 15 per cent V/V solution of sulphuric acid R. Prepare the solution daily.
Ammonium molybdate solution R6. 1005709.
Slowly add 10 ml of sulphuric acid R to about 40 ml of water R. Mix and allow to cool. Dilute to 100 ml with water R and mix. Add 2.5 g of ammonium molybdate R and 1 g of cerium sulphate R, and shake for 15 min to dissolve.

Ammonium nitrate. NH₄NO₃. (M, 80.0). 1005800. [6484/52-2].
A white or almost white, crystalline powder or colourless crystals, hygroscopic, very soluble in water, freely soluble in methanol, soluble in alcohol.
Storage: in an airtight container.

Ammonium nitrate R1. 1005801. [6484/52-2].
Complies with the requirements prescribed for ammonium nitrate R and with the following additional requirements.
Acidity. The solution of the substance is faintly acid (2.2.4).
Chlorides (2.4.4). 0.50 g complies with the limit test for chlorides (100 ppm).
Sulphates (2.4.13). 1.0 g complies with the limit test for sulphates (150 ppm).
Sulphated ash (2.4.14): maximum 0.05 per cent, determined on 1.0 g.

Ammonium oxalate. C₂H₈N₂O₄.H₂O. (M, 142.1). 1005900. [6009-70-7].
Colourless crystals, soluble in water.

Ammonium oxalate solution. 1005901.
A 40 g/l solution.

Ammonium persulphate. (NH₄)₂S₂O₈. (M, 228.2). 1006000. [7727-54-0].
White or almost white, crystalline powder or granular crystals, freely soluble in water.

White or almost white crystals or granules, hygroscopic, very soluble in water, slightly soluble in alcohol.

Ammonium phosphate solution. 1006101.
A 10 g/l solution. Prepare immediately before use.

Red powder or crystals, sparingly soluble in cold water, soluble in hot water and in alcohol.

Ammonium pyrrolidinedithiocarbamate solution. 1006301.
A 10 g/l solution. Prepare immediately before use.

Ammonium reineckate. NH₄[Cr(NCS)₄(NH₃)₂]H₂O. (M, 114.1). 1006400. [7773-06-0].
A white or almost white, crystalline powder or colourless crystals, hygroscopic, very soluble in water, slightly soluble in alcohol.
mp: about 130 °C.
Storage: in an airtight container.

Ammonium reineckate solution. 1006401.
A 10 g/l solution.

Ammonium sulphamate. NH₂SO₃NH₄. (M, 114.1). 1006500. [7773-20-2].
Colourless crystals or white or almost white granules, very soluble in water, practically insoluble in acetone and in alcohol.
pH (2.2.3): 4.5 to 6.0 for a 50 g/l solution in carbon dioxide-free water R.
Sulphated ash (2.4.14): maximum 0.1 per cent.

Ammonium sulphide solution. 1123300.
Saturate 120 ml of dilute ammonia R1 with hydrogen sulphide R and add 80 ml of dilute ammonia R1. Prepare immediately before use.

Ammonium thiocyanate. NH₄SCN. (M, 76.1). 1006700. [1762-95-4].
Colourless crystals, deliquescent, very soluble in water, soluble in alcohol.
Storage: in an airtight container.

Ammonium thiocyanate solution. 1006701.
A 76 g/l solution.

Ammonium vanadate. NH₄VO₃. (M, 117.0). 1006800. [7803-55-6]. Ammonium trioxovanadate(V).
A white to slightly yellowish, crystalline powder, slightly soluble in water, soluble in dilute ammonia R1.

Ammonium vanadate solution. 1006801.
Dissolve 1.2 g of ammonium vanadate R in 95 ml of water R and dilute to 100 ml with sulphuric acid R.

Amoxicillin trihydrate. 1103400.
See Amoxicillin trihydrate (0260).
α-Amylase. 1100800. 1,4-α-D-glucan-glucanohydrolase (EC 3.2.1.1).
A white to light brown powder.

α-Amylase solution. 1100801.
A solution of α-amylase R with an activity of 800 FAU/g.

β-Amyrin. C₂₀H₃₂O. (M, 246.7). 1141800. [559-70-6].
Olean-12-en-3β-ol.
White or almost white powder.
mp: 187 °C to 190 °C.

1-Methoxy-4-(propen-1-yl)benzene.
A white or almost white, crystalline mass up to 20 °C to 21 °C, liquid above 23 °C, practically insoluble in water, freely soluble in ethanol, soluble in ethyl acetate and in light petroleum.
"n"²₅: about 1.56.
bp: about 230 °C.
Anethole used in gas chromatography complies with the following test.
Assay. Examine by gas chromatography (2.2.28) under the conditions described in the monograph on Anise oil (0804) using the substance to be examined as the test solution. The area of the principal peak, corresponding to trans-anethole, with a retention time of about 41 min, is not less than 99.0 per cent of the total area of the peaks.

Benzenamine.
A colourless or slightly yellowish liquid, soluble in water, miscible with alcohol.
d₂₅°: about 1.02.
bp: 183 °C to 186 °C.
Storage: protected from light.

Aniline hydrochloride. C₆H₇ClN. (M, 129.6). 1147700. [142-04-1].
Benzenamine hydrochloride.
Crystals. It darkens on exposure to air and light.
mp: about 198 °C.
Storage: protected from light.

Anion exchange resin. 1007200.
A resin in chlorinated form containing quaternary ammonium groups [CH₂N+(CH₃)₃] attached to a lattice consisting of poly(methyl methacrylate). 8 per cent of divinylbenzene. It is available as spherical beads and the particle size is specified in the monograph.

Anion exchange resin R1. 1123400.
A resin containing quaternary ammonium groups [CH₂N+(CH₃)₃] attached to a lattice consisting of methacrylate.

Anion exchange resin R2. 1141900.
A conjugate of homogeneous 10 µm hydrophilic polyether particles, and a quaternary ammonium salt, providing a matrix suitable for strong anion-exchange chromatography.

Anion exchange resin for chromatography, strongly basic. 1112700.
A resin with diethylaminoethyl groups attached to a lattice consisting of poly(styrene-divinylbenzene) with about 8 per cent of divinylbenzene. It is available as spherical beads and the particle size is specified in the monograph.

Anion exchange resin for chromatography, strongly basic. 1112700.
A gel-type resin in hydroxide form containing quaternary ammonium groups [CH₂N+(CH₃)₃] attached to a polymer lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene.
Brown transparent beads.
Particle size: 0.2-1.0 mm.
Moisture content: about 50 per cent.
Total exchange capacity: minimum 1.2 meq/ml.

Anion exchange resin, weak. 1146700.
A resin with diethylaminoethyl groups attached to a lattice consisting of poly(methyl methacrylate).

4-Methoxybenzaldehyde.
An oily liquid, very slightly soluble in water, miscible with alcohol.
bp: about 248 °C.

Anisaldehyde used in gas chromatography complies with the following test.
Assay. Examine by gas chromatography (2.2.28) in the conditions described in the monograph on Anise oil (0804) the substance to be examined as the test solution. The area of the principal peak is not less than 99.0 per cent of the total area of the peaks.

Anisaldehyde solution. 1007301.
Mix in the following order, 0.5 ml of anisaldehyde R, 10 ml of glacial acetic acid R, 85 ml of methanol R and 5 ml of sulphuric acid R.

Anisaldehyde solution R1. 1007302.
To 10 ml of anisaldehyde R add 90 ml of alcohol R, mix, add 10 ml of sulphuric acid R and mix again.

p-Anisidine. C₆H₅N. (M, 123.2). 1103500. [104-94-9].
4-Methoxyaniline.
White or almost white crystals, sparingly soluble in water, soluble in ethanol.
Content: minimum 97.0 per cent of C₆H₅NO.
Caution: skin irritant, sensitisser.
Storage: protected from light, at 0 °C to 4 °C.

On storage, p-anisidine tends to darken as a result of oxidation. A discoloured reagent can be reduced and decolourised in the following way: dissolve 20 g of p-anisidine R in 500 ml of water R at 75 °C. Add 1 g of sodium sulphite R and 10 g of activated charcoal R and stir for 5 min. Filter, cool the filtrate to about 0 °C and allow to stand at this temperature for at least 4 h. Filter, wash the crystals with a small quantity of water R at about 0 °C and dry the crystals in vacuum over diphosphorus pentoxide R.

Anolyte for isoelectric focusing pH 3 to 5. 1112800.
0.1 M Glutamic acid, 0.5 M phosphoric acid.
Dissolve 14.71 g of glutamic acid R in water R. Add 33 ml of phosphoric acid R and dilute to 1000 ml with water R.

Anthracene. C₁₄H₁₀. (M, 178.2). 1007400. [120-12-7].
A white or almost white, crystalline powder, practically insoluble in water, slightly soluble in chloroform.
mp: about 218 °C.

Anthrone. C₁₄H₁₀O. (M, 194.2). 1007500. [90-44-8].
9(10H)-Anthracenone.
A pale yellow, crystalline powder.
mp: about 155 °C.

A white or almost white, granular powder or colourless, transparent crystals, soluble in water and in glycerol, freely soluble in boiling water, practically insoluble in alcohol. The aqueous solution is slightly acid.
Antimony trichloride. SbCl₃. (M, 228.1). 1007700. [10025-91-9].

Colourless crystals or a transparent crystalline mass, hygroscopic, freely soluble in ethanol. Antimony trichloride is hydrolysed by water.
Storage: in an airtight container, protected from moisture.

Antithrombin III. 1007701.

Rapidly wash 30 g of antithrombin R with two quantities, each of 15 ml of ethanol-free chloroform R, draw off the washings, and dissolve the washed crystals immediately in 100 ml of ethanol-free chloroform R, warming slightly.
Storage: over a few grams of anhydrous sodium sulphate R.

Antithrombin III solution R1. 1007702.
Solution I. Dissolve 110 g of antithrombin R in 400 ml of ethylene chloride R. Add 2 g of anhydrous aluminium oxide R, mix and filter through a sintered-glass filter (40) (2.1.2). Dilute to 500.0 ml with ethylene chloride R and mix. The absorbance (2.2.25) of the solution, determined at 500 nm in a 2 cm cell, is not greater than 0.07.
Solution II. Under a hood, mix 100 ml of freshly distilled acetyl chloride R and 400 ml of ethylene chloride R.
Mix 90 ml of solution I and 10 ml of solution II.
Storage: in brown ground-glass-stoppered bottle for 7 days. Discard any reagent in which colour develops.

Antithrombin III. 1007800. [09107-80-2].
Antithrombin III is purified from human plasma by heparin.

Antithrombin III solution R1. 1007801.
Reconstitute antithrombin III R as directed by the manufacturer and dilute with tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R to 1 IU/ml.

Antithrombin III solution R2. 1007802.
Reconstitute antithrombin III R as directed by the manufacturer and dilute with tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R to 0.5 IU/ml.

Antithrombin III solution R3. 1007803.
Reconstitute antithrombin III R as directed by the manufacturer and dilute to 0.3 IU/ml with phosphate buffer solution pH 6.5 R.

Antithrombin III solution R4. 1007804.
Reconstitute antithrombin III R as directed by the manufacturer and dilute to 0.1 IU/ml with tris(hydroxymethyl)aminomethane EDTA buffer solution pH 8.4 R.

Apigenin 7-glucoside. C₁₅H₁₀O₇. (M, 432.4). 1095900. [578-74-5]. Apigenin. 7-[β-D-Glucopyranosyl(1→5)-hydroxy-2-(4-hydroxyphenyl)-4H-1-benzopyran-4-one].
Light yellowish powder, practically insoluble in water, sparingly soluble in alcohol.
mp.: 198 °C to 201 °C.

Chromatography. Examine as prescribed in the monograph on Roman chamomile flower (0380), applying 10 µl of a 0.25 g/l solution in methanol R. The chromatogram shows in the upper third a principal zone of yellowish-green fluorescence.

Light yellowish powder; practically insoluble in water, sparingly soluble in alcohol.
mp.: about 310 °C, with decomposition.

Chromatography. Examine as prescribed in the monograph on Roman chamomile flower (0380), applying 10 µl of a 0.25 g/l solution in methanol R. The chromatogram shows in the upper third a principal zone of yellowish-green fluorescence.

Clear, almost colourless liquid.

\( d_2^0 \): about 1.091.

\( \beta_2^0 \): about 1.497.

\( [\alpha]_D^2 \): about + 12.

bp: about 263 °C.

Aromadendrene used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Tea tree oil (1837).

The content is not less than 92 per cent, calculated by the normalisation procedure.

Arsenious trioxide. As_{2}O_{3}. (M 197.8). 1008300. [1327-53-3]. Arsenious anhydride. Diarsenic trioxide.

A crystalline powder or a white or almost white mass, slightly soluble in water, soluble in boiling water.

Arsenic trioxide solution. 1008301.

Dissolve 0.50 g of arsenious trioxide R in 5 ml of dilute sodium hydroxide solution R, add 2.0 g of sodium hydrogen carbonate R and dilute to 100.0 ml with water R.

Ascorbic acid. 1008400. [50-81-7].

See Ascorbic acid (0253).

Ascorbic acid solution. 1008401.

Dissolve 50 mg in 0.5 ml of water R and dilute to 50 ml with dimethylformamide R.

Asiaticoside. C_{48}H_{78}O_{19}. (M 832.1). 1008500. [16830-15-2].

A white or almost white powder, hygroscopic, soluble in water, slightly soluble in alcohol.

mp: about 232 °C, with decomposition.

Asiaticoside used in liquid chromatography complies with the following additional test.

Assay. Examine by liquid chromatography (2.2.29) as prescribed in the monograph on Centella (1498).

The content is not less than 97.0 per cent calculated by the normalisation procedure.

Aspartic acid. 1134100. [56-84-8].

See Aspartic acid (0797).

\( l \)-Aspartyl-\( l \)-phenylalanine. C_{13}H_{16}N_{2}O_{5}. (M 280.3). 1008500. [13433-09-5]. (S)-3-Amino-\( N \)-(\( S \)-l-carboxy-\( l \)-phenylalanyl)succinamic acid.

A white or almost white powder.

mp: about 210 °C, with decomposition.

Atropine sulphate. 1159000. [5908-99-6]. See Atropine sulphate (0068).

Aucubin. C_{15}H_{23}O_{6}. (M 286.3). 1145200. [479-98-1]. [1S,4aR,5,7aS]-5-Hydroxy-7-(hydroxymethyl)-1,4a,5,7a-tetrahydrocyclopenta[c]pyran-1-yl \beta-D-glucopyranoside.

Crystals, soluble in water, in alcohol and in methanol, practically insoluble in light petroleum.

\( [\alpha]_D^2 \): about -163.

mp: about 181 °C.

Azomethine H. C_{15}H_{22}N_{2}O_{2}S_{2}. (M 445.4). 1008700. [5941-07-1]. Sodium hydrogeno-4-hydroxy-5-(2-hydroxybenzylideneamino)-2,7-naphthalenedisulphonate.

Azomethine H solution. 1008701.

Dissolve 0.45 g of azomethine H R and 1 g of ascorbic acid R with gentle heating in water R and dilute to 100 ml with the same solvent.


A yellow to dark-yellow, crystalline powder, or yellow needles, darkening on exposure to air and light, sparingly soluble in water and in alcohol, soluble in acetone, in ammonia and in solutions of alkali hydroxides.

Aucubin. 1S,4aR,5,7aS-5-Hydroxy-7-(hydroxymethyl)-1,4a,5,7a-tetrahydrocyclopenta[c]pyran-1-yl \beta-D-glucopyranoside.

Crystals, soluble in water, in alcohol and in methanol, practically insoluble in light petroleum.

\( [\alpha]_D^2 \): about -163.

mp: about 181 °C.

Azomethine H. C_{15}H_{22}N_{2}O_{2}S_{2}. (M 445.4). 1008700. [5941-07-1]. Sodium hydrogeno-4-hydroxy-5-(2-hydroxybenzylideneamino)-2,7-naphthalenedisulphonate.

Azomethine H solution. 1008701.

Dissolve 0.45 g of azomethine H R and 1 g of ascorbic acid R with gentle heating in water R and dilute to 100 ml with the same solvent.


A yellow to dark-yellow, crystalline powder, or yellow needles, darkening on exposure to air and light, sparingly soluble in water and in alcohol, soluble in acetone, in ammonia and in solutions of alkali hydroxides.

Aucubin. 1S,4aR,5,7aS-5-Hydroxy-7-(hydroxymethyl)-1,4a,5,7a-tetrahydrocyclopenta[c]pyran-1-yl \beta-D-glucopyranoside.

Crystals, soluble in water, in alcohol and in methanol, practically insoluble in light petroleum.

\( [\alpha]_D^2 \): about -163.

mp: about 181 °C.

Azomethine H. C_{15}H_{22}N_{2}O_{2}S_{2}. (M 445.4). 1008700. [5941-07-1]. Sodium hydrogeno-4-hydroxy-5-(2-hydroxybenzylideneamino)-2,7-naphthalenedisulphonate.

Azomethine H solution. 1008701.

Dissolve 0.45 g of azomethine H R and 1 g of ascorbic acid R with gentle heating in water R and dilute to 100 ml with the same solvent.


A yellow to dark-yellow, crystalline powder, or yellow needles, darkening on exposure to air and light, sparingly soluble in water and in alcohol, soluble in acetone, in ammonia and in solutions of alkali hydroxides.

Aucubin. 1S,4aR,5,7aS-5-Hydroxy-7-(hydroxymethyl)-1,4a,5,7a-tetrahydrocyclopenta[c]pyran-1-yl \beta-D-glucopyranoside.

Crystals, soluble in water, in alcohol and in methanol, practically insoluble in light petroleum.

\( [\alpha]_D^2 \): about -163.

mp: about 181 °C.
Barium hydroxide. \( \text{Ba(OH)}_2 \cdot \text{H}_2\text{O} \). \( M, 315.5 \). 1009400. [12230-71-6]. Barium dihydroxide.

Colourless crystals, soluble in water.

Barium hydroxide solution. 1009401.
A 47.3 g/l solution.

Barium nitrate. \( \text{Ba(NO}_3)_2 \). \( M, 261.3 \). 1163800. [10022-31-8].
Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

mp: about 590 °C.

Barium sulphate. 1009500. [7727-43-7]. See Barium sulphate (0010).

Benzenaldehyde. \( \text{C}_7\text{H}_6\text{O} \). \( \text{Benzaldehyde} \).
mp: about 39 °C.
bp: about 261 °C.

Benzalacetone. \( \text{C}_{10}\text{H}_{10}\text{O} \). (See 1009500).
mp: about 590 °C.

Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

[10022-31-8].

Benzaldehyde. \( \text{C}_7\text{H}_6\text{O} \).

mp: 95 °C.
soluble in alcohol, ethyl acetate and toluene.

A yellow, crystalline powder, practically insoluble in water, miscible with acetone and with ethanol.

[10022-31-8].

Benzalcohol. \( \text{C}_7\text{H}_5\text{O} \). (See 1009500).

mp: 95 °C.
soluble in alcohol.

A colourless, lachrymatory liquid, decomposed by water and in alcohol.

[10022-31-8].

Benzaldehyde. \( \text{C}_7\text{H}_6\text{O} \).

mp: about 39 °C.

barium hydroxide solution. 1009401.
A 47.3 g/l solution.

barium nitrate. \( \text{Ba(NO}_3)_2 \). \( M, 261.3 \). 1163800. [10022-31-8].
Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

mp: about 590 °C.

Barium sulphate. 1009500. [7727-43-7]. See Barium sulphate (0010).

Benzenaldehyde. \( \text{C}_7\text{H}_6\text{O} \). \( \text{Benzaldehyde} \).
mp: about 39 °C.
bp: about 261 °C.

Benzalacetone. \( \text{C}_{10}\text{H}_{10}\text{O} \). (See 1009500).
mp: about 590 °C.

Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

[10022-31-8].

Benzaldehyde. \( \text{C}_7\text{H}_6\text{O} \).

mp: 95 °C.
soluble in alcohol, ethyl acetate and toluene.

A yellow, crystalline powder, practically insoluble in water, miscible with acetone and with ethanol.

[10022-31-8].

Benzalcohol. \( \text{C}_7\text{H}_5\text{O} \). (See 1009500).

mp: 95 °C.
soluble in alcohol.

A colourless, lachrymatory liquid, decomposed by water and in alcohol.

[10022-31-8].

Benzaldehyde. \( \text{C}_7\text{H}_6\text{O} \).

mp: about 39 °C.

barium hydroxide solution. 1009401.
A 47.3 g/l solution.

barium nitrate. \( \text{Ba(NO}_3)_2 \). \( M, 261.3 \). 1163800. [10022-31-8].
Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

mp: about 590 °C.

Barium sulphate. 1009500. [7727-43-7]. See Barium sulphate (0010).

Benzenaldehyde. \( \text{C}_7\text{H}_6\text{O} \). \( \text{Benzaldehyde} \).
mp: about 39 °C.
bp: about 261 °C.

Benzalacetone. \( \text{C}_{10}\text{H}_{10}\text{O} \). (See 1009500).
mp: about 590 °C.

Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

[10022-31-8].

Benzaldehyde. \( \text{C}_7\text{H}_6\text{O} \).

mp: 95 °C.
soluble in alcohol, ethyl acetate and toluene.

A yellow, crystalline powder, practically insoluble in water, miscible with acetone and with ethanol.

[10022-31-8].

Benzalcohol. \( \text{C}_7\text{H}_5\text{O} \). (See 1009500).

mp: 95 °C.
soluble in alcohol.

A colourless, lachrymatory liquid, decomposed by water and in alcohol.

[10022-31-8].

Benzaldehyde. \( \text{C}_7\text{H}_6\text{O} \).

mp: about 39 °C.

barium hydroxide solution. 1009401.
A 47.3 g/l solution.

barium nitrate. \( \text{Ba(NO}_3)_2 \). \( M, 261.3 \). 1163800. [10022-31-8].
Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

mp: about 590 °C.
[See the information section on general monographs (cover pages)]

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**Benzylpenicillin sodium.** 1011000. [69-57-8].

See Benzylpenicillin sodium (0114).

**2-Benzylpyridine.** C_{12}H_{11}N. (M, 169.2). 1112900. [101-82-6].

Content: minimum 98.0 per cent of C_{12}H_{11}N.

A yellow liquid.

mp: 13 °C to 16 °C.

**Benzytrimethylammonium chloride.** C_{12}H_{18}ClNO_4.2H_2O. (M, 215.7).

mp: about 230 °C, with decomposition.

White or almost white powder, soluble in water.

Benzylpenicillin chloride used in liquid chromatography complies with the monograph on Matricaria oil (1836) using a 4 g/L solution in cyclohexane R.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

**Bisbenzimide.** C_{25}H_{27}Cl_3N_6O,5H_2O. (M, 533.7).

mp: 198 °C to 200 °C.

Bisbenzimide used for gas chromatography complies with the following additional test.

Assay. Gas chromatography (2.2.28) as prescribed in the monograph on Goldenseal rhizome (1831). The content is not less than 95 per cent, calculated by the normalisation procedure.

**Bergapten.** C_{12}H_{10}O. (M, 178.2).

mp: 248 °C to 251 °C.

A white or almost white, crystalline powder, practically insoluble in water.

Bergapten chloride used in liquid chromatography complies with the monograph on Matricaria oil (1836) using a 4 g/L solution in cyclohexane R.

Content: minimum 98.0 per cent of C_{12}H_{11}N.

Benzylpenicillin sodium (0114).
Boronic acid. 1011800. [10043-35-3].
See Boric acid (0001).

Boric acid solution, saturated, cold. 1011801.
To 3 g of boric acid R add 50 ml of water R and shake for 10 min. Place the solution for 2 h in the refrigerator.

Borneol. C_{15}H_{30}O. (M, 254.3). 1011900. [507-70-0].
endo-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-ol.
Colourless crystals, readily sublimes, practically insoluble in water, freely soluble in alcohol and in light petroleum.
mp: about 208 °C.

Chromatography. Examine by thin-layer chromatography (2.2.27), using silica gel G R as the coating substance. Apply to the plate 10 µl of a 1 g/l solution in toluene R. Develop over a path of 10 cm using chloroform R. Allow the plate to dry in air, spray with anisaldehyde solution R, using 10 ml for a plate 200 mm square, and heat at 100 °C to 105 °C for 10 min. The chromatogram obtained shows only one principal spot.

Bornyl acetate. C_{15}H_{20}O_{2}. (M, 196.3). 1012000. [5655-61-8].
endo-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-yl acetate.
Colourless crystals or a colourless liquid, very slightly soluble in water, soluble in alcohol.
mp: about 28 °C.

Chromatography. Examine by thin-layer chromatography (2.2.27), using silica gel G R as the coating substance. Apply to the plate 10 µl of a 1 g/l solution in toluene R. Develop over a path of 10 cm using chloroform R. Allow the plate to dry in air, spray with anisaldehyde solution R, using 10 ml for a plate 200 mm square, and heat at 100 °C to 105 °C for 10 min. The chromatogram obtained shows only one principal spot.

Boron trichloride. BCl_{3}. (M, 117.2). 1112000. [10294-34-5].
Colourless gas. Reacts violently with water. Available as solutions in suitable solvents (2-chloroethanol, methylene chloride, hexane, heptane, methanol).
[a]_{D}^{25}: about 1.420.
b.p.: about 12.6 °C.
Caution: toxic, corrosive.

Boron trichloride-methanol solution. 1112001.
A 120 g/1 solution of BCl_{3} in methanol R.
Storage: protected from light at –20 °C, preferably in sealed tubes.

Boron trifluoride. BF_{3}. (M, 67.8). 1021200. [7637-07-2].
Colourless gas.

Boron trifluoride-methanol solution. 1021201.
A 140 g/1 solution of boron trifluoride R in methanol R.
Brilliant blue. 1012200. [6104-59-2].
See acid blue 83 R.

Bromelains. 1012300. [37189-34-7].
A concentrate of proteolytic enzymes derived from Ananas comosus Merr.
A dull-yellow powder.
Activity. 1 g liberates about 1.2 g of amino-nitrogen from a solution of gelatin R in 20 min at 45 °C and pH 4.5.

Bromelains solution. 1012301.
A 10 g/1 solution of bromelains R in a mixture of 1 volume of phosphate buffer solution pH 5.5 R and 9 volumes of a 9 g/1 solution of sodium chloride R.

Bromine. Br_{2}. (M, 159.8). 1012400. [7726-95-6].
A brownish-red fuming liquid, slightly soluble in water, soluble in alcohol.
d_{20}: about 3.1.

Bromine solution. 1012401.
Dissolve 30 g of bromine R and 30 g of potassium bromide R in water R and dilute to 100 ml with the same solvent.

Bromine water. 1012402.
Shake 3 ml of bromine R with 100 ml of water R to saturation.
Storage: over an excess of bromine R, protected from light.

Bromine water R1. 1012403.
Shake 0.5 ml of bromine R with 100 ml of water R.
Storage: protected from light; use within 1 week.

Bromocresol green. C_{21}H_{14}Br_{4}O_{5}S. (M, 698). 1012600. [76-60-8].
endo-1,2,3,5′,5″-Tetrabromo-m-cresol-sulfonphthalein.
4,4′-(3H,2,1-Benzoxathiol-3-ylidene)bis(2,6-dibromo-3-methylphenol)-S,S-dioxide.
A brownish-white powder, slightly soluble in water, soluble in alcohol and in dilute solutions of alkali hydroxides.

Bromocresol green-methyl red solution. 1012602.
Dissolve 0.15 g of bromocresol green R and 0.1 g of methyl red R in 180 ml of ethanol R and dilute to 200 ml with water R.

Bromocresol green solution. 1012601.
Dissolve 50 mg of bromocresol green R in 0.72 ml of 0.1 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R.
Test for sensitivity. To 0.2 ml of the bromocresol green solution add 100 ml of carbon dioxide-free water R. The solution is blue. Not more than 0.2 ml of 0.02 M hydrochloric acid is required to change the colour to yellow.
Colour change: pH 3.6 (yellow) to pH 5.2 (blue).

Bromocresol purple. C_{19}H_{18}Br_{5}O_{3}S. (M, 540.2). 1012700. [115-40-2].
endo-1,2,3,5″-Tribromo-o-cresol-sulfonphthalein.
4,4′-(3H,2,1-Benzoxathiol-3-ylidene)bis(2-bromo-6-methylphenol)-S,S-dioxide.
A pinkish powder, practically insoluble in water, soluble in alcohol and in dilute solutions of alkali hydroxides.

Bromocresol purple solution. 1012701.
Dissolve 50 mg of bromocresol purple R in 0.92 ml of 0.1 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R.
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Test for sensitivity. To 0.2 ml of the bromocresol purple solution add 100 ml of carbon dioxide-free water and 0.05 ml of 0.2 M sodium hydroxide. The solution is bluish-violet. Not more than 0.2 ml of 0.02 M hydrochloric acid is required to change the colour to yellow.

**Colour change:** pH 5.2 (yellow) to pH 6.8 (bluish-violet).

**5-Bromo-2′-deoxyuridine.** C_{9}H_{8}BrN_{4}O_{4}. (M, 307.1). 1012500. [59-14-3]. 5-Bromo-1-(2-deoxy-D-erythro-pentofuranosyl)-1H-3Hpyrimidine-2,4-dione.

mp: about 194 °C.

Chromatography. Examine as prescribed in the monograph on Idoxuridine (0669), applying 5 µl of a 0.25 g/l solution. The chromatogram obtained shows only one principal spot.

**Bromomethoxynaphthalene.** C_{11}H_{9}BrO. (M, 266.9). 1012400. [76-59-5]. 3-Methylphenol)

mp: about 109 °C.

**Bromophenol blue.** C_{19}H_{10}Br_{4}O_{5}S. (M, 670). 1012800. [115-39-9]. 3′,3′-Dibromothymolsulfonphthalein. 4,4′-(CH_{2},1-Benzoxathiol-3-ylidene)bi(2,6-dibromophenol) S,S-dioxide.

A light orange-yellow powder, very slightly soluble in water, soluble in alcohol and in dilute solutions of alkali hydroxides.

**Bromophenol blue solution.** 1012801.

Dissolve 0.1 g of bromophenol blue R in 1.5 ml of 0.1 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R.

**Test for sensitivity.** To 0.05 ml of the bromophenol blue solution add 20 ml of carbon dioxide-free water R and 0.05 ml of 0.1 M hydrochloric acid. The solution is yellow. Not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour to bluish-violet.

**Colour change:** pH 2.8 (yellow) to pH 4.4 (bluish-violet).

**Bromophenol blue solution R1.** 1012901.

Dissolve 50 mg of bromophenol blue R in a mixture of 4 ml of 0.02 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R.

**Test for sensitivity.** To 0.3 ml of bromophenol blue solution R1 add 100 ml of carbon dioxide-free water R. The solution is yellow. Not more than 0.1 ml of 0.02 M sodium hydroxide is required to change the colour to blue.

**Colour change:** pH 5.8 (yellow) to pH 7.4 (blue).

**Bromophenol blue solution R2.** 1012902.

A 10 g/l solution in dimethylformamide R.

**Bromophenol blue solution R3.** 1012903.

Warm 0.1 g of bromophenol blue R with 3.2 ml of 0.05 M sodium hydroxide and 5 ml of alcohol (90 per cent V/V) R. After solution is effected, dilute to 250 ml with alcohol (90 per cent V/V) R.

**BRP indicator solution.** 1013000.

Dissolve 0.2 g of bromophenol blue R, 20 mg of methyl red R and 0.2 g of phenolphthalein R in alcohol R and dilute to 100 ml with the same solvent. Filter.

**Brucine.** C_{23}H_{26}N_{2}O_{4},2H_{2}O. (M, 430.5). 1013100. [357-57-3]. 10,11-Dimethoxytryptamine.

Colourless crystals, slightly soluble in water, freely soluble in alcohol.

**Bromophos.** C_{10}H_{12}BrCl_{2}O_{3}PS. (M, 366.0). 1123700. [2104-96-3].

A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

**Bromophos-ethyl.** C_{12}H_{14}BrCl_{2}O_{3}PS. (M, 394.0). 1123800. [4824-78-6].

A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

**Bromothymol blue.** C_{8}H_{8}BrCl_{2}O_{3}PS. (M, 624). 1012900. [76-59-5]. 3′,3′-Dibromothymolsulfonphthalein. 4,4′-(CH_{2},1-Benzoxathiol-3-ylidene)bi(2-bromo-6-isopropyl-3-methylphenol) S,S-dioxide.

A reddish-pink or brownish powder, practically insoluble in water, soluble in alcohol and in dilute solutions of alkali hydroxides.

**Bromothymol blue solution R1.** 1012901.

Dissolve 50 mg of bromothymol blue R in a mixture of 4 ml of 0.02 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R.

**Test for sensitivity.** To 0.3 ml of bromothymol blue solution R1 add 100 ml of carbon dioxide-free water R. The solution is yellow. Not more than 0.1 ml of 0.02 M sodium hydroxide is required to change the colour to blue.

**Colour change:** pH 5.8 (yellow) to pH 7.4 (blue).

**Bromothymol blue solution R2.** 1012902.

A 10 g/l solution in dimethylformamide R.

**Bromothymol blue solution R3.** 1012903.

Warm 0.1 g of bromothymol blue R with 3.2 ml of 0.05 M sodium hydroxide and 5 ml of alcohol (90 per cent V/V) R. After solution is effected, dilute to 250 ml with alcohol (90 per cent V/V) R.

**Butanal.** C_{2}H_{4}O. (M, 72.1). 1134400. [123-72-8].

Butyraldehyde.

d_{20}^{20}: 0.806.

n_{D}^{20}: 1.380.

bp: 75 °C.

**Butanol.** C_{4}H_{10}O. (M, 74.1). 1013200. [71-36-3]. n-Butanol.

A clear, colourless liquid, miscible with alcohol.

d_{20}^{20}: about 0.81.

bp: 116 °C to 119 °C.

**2-Butanol R1.** C_{4}H_{10}O. (M, 74.1). 1013301. [78-92-2]. sec-Butyl alcohol.

Content: minimum 99.0 per cent of C_{4}H_{10}O.

A clear, colourless liquid, soluble in water, miscible with alcohol.

d_{20}^{20}: about 0.81.

Distillation range (2.2.11). Not less than 95 per cent distils between 99 °C and 100 °C.

**Assay.** By gas chromatography as described in the monograph on Isopropyl alcohol (0970).

**Butyl acetate.** C_{4}H_{8}O. (M, 116.2). 1013400. [123-86-4].

A clear, colourless liquid, flammable, slightly soluble in water, miscible with alcohol.

d_{20}^{20}: about 0.88.

n_{D}^{20}: about 1.395.

Distillation range (2.2.11). Not less than 95 per cent distils between 123 °C and 126 °C.

**Butyl acetate R1.** 1013401.

A clear, colourless liquid, flammable, slightly soluble in water, miscible with alcohol.

d_{20}^{20}: about 0.883.

See the information section on general monographs (cover pages)
Dihydro-2(3-0ily liquid, miscible with water, soluble in methanol.

Butanol: maximum 0.2 per cent, determined by gas chromatography.

n-Butyl formate: maximum 0.1 per cent, determined by gas chromatography.

n-Butyl propionate: maximum 0.1 per cent, determined by gas chromatography.

Water: maximum 0.1 per cent.

Assay: minimum 99.5 per cent of C₈H₁₈O₂, determined by gas chromatography.

Butyramine. C₄H₁₁N. ([Ge ner a l N ot i c e s (1) a p p l y t o al l m o n o g r a p h s a n d t h e r t e x t s

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Clear, colourless solution.

[97-88-1]. Butyl 2-methylpropenoate.

An oily liquid, miscible with water and with alcohol.

Flammable liquid, soluble in organic solvents.

[75-91-2]. 1,1-Dimethylethylhydroperoxide.

Content: minimum 99.0 per cent of C₈H₈O₂.

Butanoic acid. C₄H₈O₂. (Butyric acid.

1,1-Dimethylethyl methyl ether. R. See

1,1-dimethylethyl methyl ether R.

Butyl propionate. [1305-62-0]. Calcium dihydroxide.

Storage: in an airtight container, protected from moisture.

Calcium hydroxide. Ca(OH)₂. (M, 74.1). 1014500.

Calcium hydroxide, anhydrous. CaCl₂. (M, 111.0). 1014800.

Calcium hydroxide solution. 1014602.

Calcium hydroxide solution 0.01 M. 1014601.

Calcium hydroxide solution 0.02 M. 1014603.

Calcium hydroxide solution 0.1 M. 1014600.

Calcium chloride. 1014500. [471-34-1].

Calcium chloride solution. 1014601.

A 73.5 g/l solution.

Calcium chloride solution 0.01 M. 1014602.

Dissolve 0.147 g of calcium chloride R in water R and dilute to 100.0 ml with the same solvent.

Calcium chloride solution 0.02 M. 1014603.

Dissolve 2.94 g of calcium chloride R in 900 ml of water R, adjust to pH 6.0 to 6.2 and dilute to 1000.0 ml with water R.

Storage: at 2 °C to 8 °C.

Calcium chloride R1. CaCl₂·2H₂O. (M, 183.1). 1014700.

Calcium chloride tetrahydrate. Content: maximum 0.05 ppm of Fe.

Calcium chloride, anhydrous. CaCl₂. (M, 111.0). 1014800. [10043-52-4].

Content: minimum 98.0 per cent of CaCl₂, calculated with reference to the dried substance.

White or almost white granules, deliquescent, very soluble in water, freely soluble in alcohol and in methanol.

Loss on drying (2.2.32): maximum 5.0 per cent, determined by drying in an oven at 200 °C.

Storage: in airtight container, protected from moisture.

Calcium hydroxide. Ca(OH)₂. (M, 74.1). 1015000.

Calcium hydroxide. 1015000. [1305-62-0]. Calcium dihydroxide.

A white or almost white powder, almost completely soluble in 600 parts of water.

Calcium hydroxide solution. 1015001.

A freshly prepared saturated solution.

Calcium lactate. 1015100. [41372-22-9].

See Calcium lactate pentahydrate (0468).
Camphene. \( \text{C}_{10}\text{H}_{16} \). A white or almost white powder, soluble in about 1500 parts of water, practically insoluble in alcohol. When mixed with half its mass of water it rapidly solidifies to a hard and porous mass.

**Calcium sulphate.** \( \text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O} \). (M. 145.1). \( 1015200. \) [10034-76-1]. Calcium sulphate hemihydrate.

**Camphor.** \( \text{C}_{10}\text{H}_{16}\text{O} \). (M. 136.2). \( 1157200. \) [10031-30-8]. (1R,4S)-(−)-10-Bo-nornesulphonic acid. Reychler’s acid.

**Calconecarboxylic acid.** \( \text{C}_{21}\text{H}_{14}\text{N}_{2}\text{O}_{7}\text{S},3\text{H}_2\text{O} \). (M. 492.5). \( 1015300. \) [3737-95-9]. 2-Hydroxy-1-(2-hydroxy-4-sulpho-1-naphthalene-3-carboxylic acid.

**Calcium sulphate solution.** \( 1015201. \) Shake 5 g of calcium sulphate R with 100 ml of water R for 1 h and filter.

**Calcaproic acid.** \( \text{C}_{10}\text{H}_{14}\text{O}_{3} \). (M. 172.3). \( 1142000. \) [334-48-5]. Decanoic acid.

**Camphene used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848).

The content of capric acid is not less than 98 per cent, calculated by the normalisation procedure.

**Capric alcohol.** \( 1024700. \) See Decanol R.

**Caproic acid.** \( \text{C}_{6}\text{H}_{12}\text{O}_{2} \). (M. 116.2). \( 1142100. \) [142-62-1]. Hexanoic acid.

**Capric acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848).

The content of capric acid is not less than 98 per cent, calculated by the normalisation procedure.

**Caprylic acid.** \( \text{C}_{8}\text{H}_{16}\text{O}_{2} \). (M. 144.2). \( 1142200. \) [124-07-2]. Octanoic acid.

**Caprylic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848).

The content of caprylic acid is not less than 98 per cent, calculated by the normalisation procedure.

**Capsaicin.** \( \text{C}_{16}\text{H}_{18}\text{NO}_{3} \). (M. 255.4). \( 1147900. \) [404-86-4]. (E)-N-[[(4-Hydroxy-3-methoxyphenyl)methyl]-8-methylnon-6-enamide.

White or almost white, crystalline powder, practically insoluble in water, freely soluble in ethanol. mp: about 65 °C.

**Capsaicin used in the assay in Capsicum (1859) complies with the following additional requirement.**

**Assay.** Examine by liquid chromatography (2.2.29) as prescribed in the monograph on Capsicum (1859). The content of capsaicin is not less than 95.0 per cent, calculated by the normalisation procedure.

Crystals, practically insoluble in water, freely soluble in acetone, slightly soluble in ethanol. mp: about 245 °C.

Carbomer. 1015500. [9007-20-9].

A cross-linked polymer of acrylic acid; it contains a large proportion (56 per cent to 68 per cent) of carboxylic acid (CO₂H) groups after drying at 80 °C for 1 h. Average relative molecular mass about 3 × 10⁶.

pH (2.2.3): about 3 for a 10 g/l suspension.


Carbon dioxide R1. CO₂ (M, 44.01). 1015700.

Content: minimum 99.995 per cent V/V of CO₂.

Carbon monoxide: less than 25 ppm.

Nitric oxide: less than 1 ppm.

Carbon dioxide R2. CO₂ (M, 44.01). 1134500.

Content: minimum 99 per cent V/V of CO₂.

Carbon disulphide. CS₂ (M, 76.1). 1015800. [75-15-0].

A colourless or yellowish, flammable liquid, practically insoluble in water, miscible with ethanol. slightly soluble in ethanol.

bp: 46 °C to 47 °C.

Carbon for chromatography, graphitised. 1015900.

Carbon chains having a length greater than C₉ with a particle size of 400 µm to 850 µm.

Relative density: 0.72.

Surface area: 10 m²/g.

Do not use at a temperature higher than 400 °C.

Carbon for chromatography, graphitised R1. 1153500.

Porous spherical carbon particles comprised of flat sheets of hexagonally arranged carbon atoms.

Particle size: 57 µm.

Pore volume: 0.7 cm³/g.

Carbon monoxide. CO. (M, 28.01). 1016000. [630-08-0].

Content: minimum 99.97 per cent V/V of CO.

Carbon monoxide R1. CO. (M, 28.01). 1134600. [630-08-0].

Content: minimum 99 per cent V/V of CO.

Carbon tetrachloride. CCl₄ (M, 153.8). 1016100. [56-23-5].

Tetrachloromethane.

A clear, colourless liquid, practically insoluble in water, miscible with alcohol.

d₂₀: 1.595 to 1.598.

bp: 76 °C to 77 °C.


Yellowish liquid, practically insoluble in water, miscible with organic solvents.

d₂₀: about 1.27.

For the monograph Wool Fat (0134), a suitable certified reference solution (10 ng/µl in iso-octane) may be used.
[\text{oxatricyclo[8.2.0.0^4,6]dodecane}]. (11149000. [1139-30-6]. (-)-C\text{15H24O}. (of the total area of the peaks.

- Examine by gas chromatography (2.2.28) as prescribed in the monograph on Peppermint oil (0405) using the substance to be examined as the test solution.

**Content**: minimum 98.0 per cent, calculated by the normalisation procedure.

**Carvone R1.** 1016500. [2244-16-8].

- Complies with the requirements described for carvone R with the following additional test.

**Assay.** Gas chromatography (2.2.28) as prescribed in the test for chiral purity in the monograph on Caraway oil (1817).

**Content**: minimum 99 per cent.


- Liquid.

d\text{D}^20: about 0.965.

n\text{D}^20: about 1.4988.

[\alpha\text{I}^2]D: about −62.

bp: about 230 °C.

**Assay.** Gas chromatography (2.2.28) as prescribed in the test for chiral purity in the monograph on Caraway oil (1817).

**Content**: minimum 99 per cent.


- An oily liquid, practically insoluble in water, miscible with alcohol.

- β-Caryophyllene used in gas chromatography complies with the following additional test.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Clove oil (1091) using the substance to be examined as the test solution.

The area of the principal peak is not less than 90.0 per cent of the total area of the peaks.


- Colourless, fine crystals with lumps.

mp: 62 °C to 63 °C.

**Assay.** Gas chromatography (2.2.28) as prescribed in the monograph on Turpentine oil, Pinus pinaster type (1627).

The content is not less than 99.0 per cent, calculated by the normalisation procedure.

**Casein.** 1016600. [9000-71-9].

A mixture of related phosphoproteins obtained from milk.

White or almost white, amorphous powder or granules, very slightly soluble in water and in non-polar organic solvents. It dissolves in concentrated hydrochloric acid giving a pale-violet solution. It forms salts with acids and bases. Its isoelectric point is at about pH 4.7. Alkaline solutions are laveroratory.

**Casticin.** C\text{15H30O}\text{5}. (M. 374.3). 1162200. [479-91-4]. 5-Hydroxy-2-(3-hydroxy-4-methoxyphenyl)-3,6,7-trimethoxy-4\text{H}-1-benzopyran-4-one.

Yellow crystals.

**Catalpol.** C\text{15H30O}_\text{5}. (M. 362.3). 1142300. [2415-24-9]. (1aS, 1bS,2S,5aR,6S,5aS)-6-Hydroxy-1a-(hydroxymethyl)-1a,1b,2, 5a,6,6a-hexahydroxireno[4,5]cyclopenta[1,2]clpyran-2-yl β-0-glucopyranoside.

mp: 203 °C to 205 °C.

**Carvone.** C\text{10H14O}. (M. 150.2). 1160500. [6485-40-1]. (−)-p-Mentha-1(6),8-dien-2-one. (5R)-2-Methyl-5-(1-methylethenyl)cyclohex-2-enone.

- Gas chromatography (2.2.28) as prescribed in the test for chiral purity in the monograph on Caraway oil (1817).

**Catechol.** C\text{6H4O}. (M. 150.2). 1113100. 0.1 M β-Alanine.

Dissolve 8.9 g of β-alanine R in water R and dilute to 1000 ml with the same solvent.

**Cation exchange resin.** 1016700.

A resin in protonated form with sulphonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene. It is available as beads and the particle size is specified after the name of the reagent in the tests where it is used.

**Cation exchange resin R1.** 1121900.

A resin in protonated form with sulphonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 4 per cent of divinylbenzene. It is available as beads and the particle size is specified after the name of the reagent in the tests where it is used.

**Cation-exchange resin, strong.** 1156800.

A strong cation-exchange resin in protonated form with sulphonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene. The particle size is specified after the name of the reagent in the tests where it is used.

**Cation-exchange resin (calcium form), strong.** 1104600.

A resin in calcium form with sulphonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene. The particle size is specified after the name of the reagent in the tests where it is used.

**Cellulose for chromatography.** 1016800. [9004-34-6].

A fine, white or almost white, homogeneous powder with an average particle size less than 30 μm.

**Preparation of a thin layer.** Suspend 15 g in 100 ml of water R and homogenise in an electric mixer for 60 s. Coat carefully cleaned plates with a layer 0.1 mm thick using a spreading device. Allow to dry in air.

**Cellulose for chromatography R1.** 1016900.

Microcrystalline cellulose. A fine, white or almost white, homogeneous powder with an average particle size less than 30 μm.

**Preparation of a thin layer.** Suspend 25 g in 90 ml of water R and homogenise in an electric mixer for 60 s. Coat carefully cleaned plates with a layer 0.1 mm thick using a spreading device. Allow to dry in air.
Cellulose for chromatography. F254. 1017000.
Microcrystalline cellulose F254. A fine, white or almost white, homogenous powder with an average particle size less than 30 µm, containing a fluorescent indicator having an optimal intensity at 254 nm.
Preparation of a thin layer. Suspend 25 g in 100 ml of water R and homogenise using an electric mixer for 60 s. Coat carefully cleaned plates with a layer 0.1 mm thick using a spreading device. Allow to dry in air.

Chloral hydrate. 1017900.

Chloral hydrate solution. 1018000. [7080-50-4].
See Tosylchloramide sodium (0381).

Chloramine solution. 1018001.
A 20 g/l solution. Prepare immediately before use.

Chloramine solution R1. 1018002.
A 0.1 g/l solution of chloramine R. Prepare immediately before use.

Chloramine solution R2. 1018003.
A 0.2 g/l solution. Prepare immediately before use.

Chlordane. C10H6Cl8O4P. (M, 581.6). 1124100. [12789-03-6]. bp: about 175 °C. mp: about 106 °C. A suitable certified reference solution of technical grade (10 ng/µl in iso-octane) may be used.

Chlordiazepoxide. 1113200. [58-25-3].
See Chlordiazepoxide (0656).

Chlorfenvinphos. C12H14Cl3O4P. (M, 359.6). 1124200. [470-90-6]. A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Chloroacetaldehyde. C3H5ClO. (M, 94.5). 1018200. [79-11-8]. Colourless or white or almost white crystals, deliquescent, very soluble in water, soluble in alcohol.
Storage: in an air tight container.

Crystals, soluble in hot water, freely soluble in alcohol.
mp: about 71 °C.

Chlorobenzenesulphonamide. C6H5ClO2S. (M, 191.6). 1097400. [98-64-6]. White or almost white powder.
mp: about 145 °C.

Chlorobenzonic acid. C7H5ClO2. (M, 156.6). 1139300. [118-91-2]. Soluble in water, slightly soluble in ethanol.
bp: about 285 °C.
mp: about 140 °C.

Chlorobutanol. 1018400. [57-15-8].
See Anhydrous chlorobutanol (0382).

Chloro-2-deoxy-D-glucose. C9H10ClO4. (M, 198.6). 1134700. [14685-79-1]. A white or almost white crystalline, very hygroscopic powder, soluble in water and in dimethyl sulphoxide, practically insoluble in alcohol.

δ2H: about 1.197.
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See the information section on general monographs (cover pages)
5-Chloroquinolin-8-ol. C₇H₅ClNO. (M, 179.6). 1156900. [130-165]. 5-Chloroquinoline.
Sparingly soluble in cold dilute hydrochloric acid.
mp: about 123 °C.
Content: minimum 95.0 per cent of C₇H₅ClNO.

5-Chlorosalicicylic acid. C₇H₆ClO₃. (5-Chlorosalicylic acid. [75-77-4]. C₇H₅ClO₃.
A clear, colourless liquid, fuming in air.
mp: about 173 °C.

Chlorothiazide. 1121200. [58-94-6].
See Chlorothiazide (0385).
Chlorotrimethylsilane. C₃H₉ClSi. (Chlorotrimethylsilane. [1333-82-0]. C₃H₉ClSi.
A reddish-brown powder, soluble in water, slightly soluble in alcohol.

Chromic acid. Cr₂O₇. (Chromic acid. [10060-12-5]. Cr₂O₇.
A brownish-black powder, soluble in water, freely soluble in alcohol.
Storage: protected from humidity and oxidising agents.

Chromic acid cleansing mixture. 1019700.
A saturated solution of chromic trioxide R in sulphuric acid R.

Chromic potassium sulphate. Cr₂O₇·12H₂O. (Chromic potassium sulphate. [1667-99-8]. Cr₂O₇·12H₂O.
Large, violet-red to black crystals, freely soluble in water, practically insoluble in alcohol.

Chromotrope II B. C₁₆H₉N₃Na₂O₁₀S₂. (Chromotrope II B. [513-4]. C₁₆H₉N₃Na₂O₁₀S₂.
A yellowish-red colour, practically insoluble in alcohol.

Chromotrope II B solution. 1020201.
A 0.05 g/l solution in sulphuric acid R.
4.1.1. Reagents

**Chromotropic acid, sodium salt.** \( \text{C}_{16}\text{H}_{22}\text{Na}_{2}\text{O}_{8},2\text{H}_{2}\text{O.} (M, 400.3) \text{ 1020300.} \ [5808-22-0]. \)**

Schultz No. 1136.

Disodium 4,5-dihydroxynaphthalene-2,7-disulphonate dihydrate. Disodium 1,8-dihydroxynaphthalene-3,6-disulphonate dihydrate.

A yellowish-white powder, soluble in water, practically insoluble in alcohol.

**Chromotropic acid, sodium salt solution.** 1020301.

Dissolve 0.60 g of chromotropic acid, sodium salt \( R \) in about 80 ml of water \( R \) and dilute to 100 ml with the same solvent. Use this solution within 24 h.

**Chromotropic acid-sulphuric acid solution.** 1020302.

Dissolve 5 mg of chromotropic acids sodium salt \( R \) in 10 ml of a mixture of 9 ml of sulphuric acid \( R \) and 4 ml of water \( R \).

**Chrysanthenin.** \( \text{C}_{21}\text{H}_{21}\text{ClO}_{11}. (M, 485.5). 1134800. \ [7084-24-4]. \)**

Kuromanin chloride. 2-(3,4-Dihydroxyphenyl)-3-β-D-glucopyranosyl)oxy-5,7-dihydroxy-1-benzopyrylium chloride.

A reddish-brown crystalline powder, soluble in water and in light petroleum, soluble in alcohol.

Absorbance (2.2.25). A 0.01 g/l solution in a mixture of 1 volume of hydrochloric acid \( R \) and 999 volumes of methanol \( R \) shows a maximum at 528 nm.

**α-Chymotrypsin for peptide mapping.** 1142400.

α-Chymotrypsin of high purity, treated to eliminate trypic activity.

**Cinchonidine.** \( \text{C}_{19}\text{H}_{22}\text{N}_{2}\text{O}. (M, 294.4). 1125000. \ [140-10-3]. \)**

(Cinchonine. mp: about 208 °C, with decomposition.

α

**α-Methyl-4-(1-methylethyl)-7-oxabicyclo[2.2.1]heptane.** 1125000.

1-Methyl-4-(1-methylethyl)-7-oxabicyclo[2.2.1]heptane.

A colourless liquid.

\( d_{20}^{20}: \) about 1.048 to 1.051.

mp: about 212 °C.

Storage: protected from light.

**Cinnamaldehyde.** \( \text{C}_{9}\text{H}_{8}\text{O}. (M, 132.2). 1020700. \ [104-55-2]. \)**

(3-Phenylprop-2-enal. 3-Phenylpropenal.

A yellowish to greenish-yellow, oily liquid, slightly soluble in water, very soluble in alcohol.

\( d_{20}^{20}: \) 1.048 to 1.051.

mp: about 133 °C.

Storage: protected from light.

**Cineole.** \( \text{C}_{10}\text{H}_{18}\text{O}. (M, 154.3). 1124600. \ [470-82-6]. \)**

(E)-3-Phenylprop-2-enamide.

A colourless liquid, practically insoluble in water, freely soluble in ethanol (96 per cent).

mp: about 149 °C.

Storage: protected from light.

**Cinnamyl acetate.** \( \text{C}_{9}\text{H}_{12}\text{O}_{2}. (M, 176.2). 1124700. \ [103-54-8]. \)**

3-Phenylprop-2-enylacetate.

A colourless liquid.

mp: about 154 °C.

Storage: protected from light.
Citr. $\text{C}_{10}$H$_{18}$O. ($M$, 152.2). 1020800. [5392-40-5]. Mixture of (2E)- and (2Z)-7-Dimethylhexa-2,6-di-enal.

A light yellow liquid, practically insoluble in water, miscible with alcohol and with glycerol.

**Chromatography.** Examine by thin-layer chromatography (2.2.27), using silica gel $G_{F_{254}}$ as the coating substance.

Apply to the plate 10 µl of a 1 g/1 solution in toluene $R$. Develop over a path of 15 cm using a mixture of 15 volumes of ethyl acetate $R$ and 85 volumes of toluene $R$. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The chromatogram obtained shows only one principal spot.

**Citr. used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Citronella oil (1609).

The content of citral (neral + geranial) is not less than 95.0 per cent calculated by the normalisation procedure.

**Citrated rabbit plasma.** 1020900.

Collect blood by intracardiac puncture from a rabbit kept fasting for 12 h, using a plastic syringe with a No. 1 needle containing a suitable volume of 38 g/1 solution of sodium citrate $R$ so that the final volume ratio of citrate solution to blood is 1: 9. Separate the plasma by centrifugation at 1500 g to 1800 g at 15 °C to 20 °C for 30 min.

**Storage:** at 0 °C to 6 °C; use within 4 h of collection.

**Citic acid.** 1021000. [5949-29-1]. See Citric acid monohydrate (0456).

When used in the limit test for iron, it complies with the following additional requirement.

Dissolve 0.5 g in 10 ml of water $R$, add 0.1 ml of thioglycolic acid $R$, mix and make alkaline with ammonia $R$. Dilute to 20 ml with water $R$. No pink colour appears in the solution.

**Citic acid, anhydrous.** 1021200. [77-92-9]. See Anhydrous citric acid (0455).

**Citronella.** $\text{C}_{15}$H$_{20}$O. ($M$, 154.3). 1113300. [106-23-0]. 3,7-Dimethyl-6-octen-1-ol.

Very slightly soluble in water, soluble in alcohols.

$\delta_{20}^{\rho}$: 0.848 to 0.856.

$\eta_{20}^\circ$: about 1.446.

**Citronella used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Citronella oil (1609).

The content is not less than 95.0 per cent calculated by the normalisation procedure.

**Citronellol.** $\text{C}_{15}$H$_{20}$O. ($M$, 156.3). 1134900. [106-22-9]. 3,7-Dimethyl-6-octen-1-ol.

A clear, colourless liquid, practically insoluble in water, miscible with alcohol.

$\delta_{20}^{\rho}$: 0.857.

$\eta_{20}^\circ$: 1.456.

**bp:** 220 °C to 222 °C.

**Citronellol used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Citronella oil (1609).

The content is not less than 95.0 per cent calculated by the normalisation procedure.

**Storage:** in an airtight container, protected from light.

**Citronellyl acetate.** $\text{C}_{16}$H$_{22}$O$_2$. ($M$, 198.3). 1135000. [150-84-5]. 3,7-Dimethyl-6-octen-1-yl acetate.

$\delta_{20}^{\rho}$: 0.890.

$\eta_{20}^\circ$: 1.443.

**bp:** 229 °C.

**Citronellyl acetate used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Citronella oil (1609).

The content is not less than 97.0 per cent calculated by the normalisation procedure.

**Storage:** in an airtight container, protected from light.

**Citrophen.** $\text{C}_{15}$H$_{24}$O. ($M$, 206.2). 1021300. [487-06-9]. Limetin. 5,7-Dimethoxy-2H-1-benzopyran-2-one.

Needle-shaped crystals, practically insoluble in water and in light petroleum, freely soluble in acetone and in alcohol.

**mp:** about 145 °C.

**Citrophen hydrochloride.** $\text{C}_{15}$H$_{24}$ClO. ($M$, 239.2). 1021400. [487-07-0]. Limetin hydrochloride. 5,7-Dimethoxy-2H-1-benzopyran-2-one hydrochloride.

**mp:** about 245 °C.

**Citrophen hydrobromide.** $\text{C}_{15}$H$_{24}$BrO. ($M$, 264.2). 1021500. [487-08-1]. Limetin hydrobromide. 5,7-Dimethoxy-2H-1-benzopyran-2-one hydrobromide.

**mp:** about 249 °C.

**Clobetasol propionate.** $\text{C}_{25}$H$_{32}$ClFO$_5$. ($M$, 467.0). 1097700. [25122-46-7]. 21-Chloro-9-fluoro-11β,17-dihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-propionate.

A white or almost white crystalline powder, insoluble in water, soluble in alcohol and in acetone.

**mp:** about 196 °C.

**Citrophen propionate.** $\text{C}_{15}$H$_{24}$ClO. ($M$, 239.2). 1021600. [487-07-0]. Limetin propionate. 5,7-Dimethoxy-2H-1-benzopyran-2-one propionate.

**mp:** about 196 °C.

**Coagulation factor V solution.** 1021400.

Coagulation factor V solution may be prepared by the following method or by any other method which excludes factor VIII.

Prepare the factor V reagent from fresh oxalated bovine plasma, by fractionation at 4 °C with a saturated solution of ammonium sulphate $R$ prepared at 4 °C. Separate the fraction which precipitates between 38 per cent and 50 per cent of saturation, which contains factor V without significant contamination with factor VIII. Remove the ammonium sulphate by dialysis and dilute the solution with a 9 g/1 solution of sodium chloride $R$ to give a solution containing between 10 per cent and 20 per cent of the quantity of factor V present in fresh human normal plasma.

**Determination of factor V content.** Prepare two dilutions of the preparation of factor V in.imidazole buffer solution pH 7.3 R containing 1 volume of the preparation in 10 volumes and in 20 volumes of the buffer solution respectively. Test each dilution as follows: mix 0.1 ml of plasma substrate deficient in factor V $R$, 0.1 ml of the solution to be examined, 0.1 ml of thromboplastin $R$ and 0.1 ml of a 3.5 g/1 solution of calcium chloride $R$ and measure the coagulation times, i.e. the interval between the moment at which the calcium chloride solution is added and the first indication of the formation of fibrin, which may be observed visually or by means of a suitable apparatus.

In the same manner, determine the coagulation time (in duplicate) of four dilutions of human normal plasma in imidazole buffer solution pH 7.3 R, containing respectively, 1 volume in 10 (equivalent to 100 per cent of factor V), 1 volume in 50 (20 per cent), 1 volume in 100 (10 per cent), and 1 volume in 1000 (1 per cent). Using two-way logarithmic paper plot the average coagulation times for each dilution of human plasma against the equivalent percentage of factor V and read the percentage of factor V for the two dilutions...
the factor V solution by interpolation. The mean of the two results gives the percentage of factor V in the solution to be examined.

**Storage**: in the frozen state at a temperature not higher than –20 °C.

**Cobalt chloride**: CoCl₂·6H₂O. (M, 237.9). 1021600. [7791-13-1].
A red, crystalline powder or deep-red crystals, very soluble in water, soluble in alcohol.

**Cobalt nitrate**: Co(NO₃)₂·6H₂O. (M, 291.0). 1021700. [10026-22-9].
Small garnet-red crystals, very soluble in water.

**Codeine**: 1021800. [6059-47-8].
See Codeine (0076).

**Codeine phosphate**: 1021900. [52-28-8].
See Codeine phosphate hemihydrate (0074).

**Congo red**: C₃H₁₇N₂Na₂O₅S₂· (M, 697). 1022000. [573-58-0].
Schultz No. 360.
Colour Index No. 22120.
Disodium (biphenyl-4,4′-diyl-bis-2,2′-azoniosbis(1-aminonaphthalene-4-sulphonate).
A brownish-red powder, soluble in water.

**Congo red solution**: 1022002.
Immerse strips of filter paper for a few minutes in congo red solution R. Allow to dry.

**Congo red solution**: 1022001.
Dissolve 0.1 g of congo red R in a mixture of 20 ml of alcohol R and water R and dilute to 100 ml with water R.
Test for sensitivity. To 0.2 ml of the congo red solution add 100 ml of carbon dioxide-free water R and 0.3 ml of 0.1 M hydrochloric acid. The solution is blue. Not more than 0.3 ml of 0.1 M sodium hydroxide is required to change the colour to pink.
Colour change: pH 3.0 (blue) to pH 5.0 (pink).

**Coomassie blue**: 1001400. [3861-73-2].
See acid blue 92 R.

**Coomassie blue solution**: 1001401.
See acid blue 92 solution R.

**Coomassie staining solution**: 1012201.
A 1.25 g/1 solution of acid blue 83 R in a mixture consisting of 1 volume of glacial acetic acid R, 4 volumes of methanol R and 5 volumes of water R. Filter.

**Copper**: Cu. (A, 63.55). 1022100. [7440-50-8].
Cleaned foil, turnings, wire or powder of the pure metal of electrolytic grade.

**Copper acetate**: C₉H₆CuO₄.H₂O. (M, 199.7). 1022200. [142-71-2].
Blue-green crystals or powder, freely soluble in boiling water, soluble in water and in alcohol, slightly soluble in glycerol (85 per cent).

**Copper edetate solution**: 1022300.
To 2 ml of a 20 g/1 solution of copper acetate R add 2 ml of 0.1 M sodium edetate and dilute to 50 ml with water R.

**Copper nitrate**: Cu(NO₃)₂·3H₂O. (M, 241.6). 1022400. [10031-43-3].
Cobalt nitrate dinitrate trihydrate.
Dark blue crystals, hygroscopic, very soluble in water giving a strongly acid reaction, freely soluble in alcohol and in dilute nitric acid.

**Storage**: in an airtight container.

**Copper sulphate**: CuSO₄·5H₂O. (M, 249.7). 1022500. [7758-99-8].
A blue powder or deep-blue crystals, slowly efflorescent, very soluble in water, slightly soluble in alcohol.

**Copper sulphate solution**: 1022501.
A 125 g/1 solution.

**Copper tetrammine, ammoniacal solution of**: 1022600.
Dissolve 34.5 g of copper sulphate R in 100 ml of water R and, whilst stirring, add dropwise, concentrated ammonium R until the precipitate which forms dissolves completely.
Keeping the temperature below 20 °C, add dropwise with continuous shaking 30 ml of strong sodium hydroxide solution R. Filter through a sintered-glass filter (40) (2.1.2), wash with water R until the filtrate is clear and take up the precipitate with 200 ml of concentrated ammonium R. Filter through a sintered-glass filter (2.1.2) and repeat the filtration to reduce the residue to a minimum.

**Cortisone acetate**: 1097800. [50-04-4].
See Cortisone acetate (0321).

**Coumarin**: C₉H₆O₃. (M, 164.2). 11124800. [56-72-4].
mp: 91 °C to 92 °C.
A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

**o-Coumaric acid**: C₈H₆O₃. (M, 164.2). 11125400. [614-60-8].
(E)-2-Hydroxycinnamic acid. (E)-3-(4-Hydroxyphenyl)prop-2-enoic acid.
White or almost white powder.
mp: about 217 °C.

**p-Coumaric acid**: C₈H₆O₃. (M, 164.2). 11157500. [7400-08-0].
4-Hydroxycinnamic acid. 3-(4-Hydroxyphenyl)-prop-2-enoic acid.
White or almost white needles, practically insoluble in water, soluble in acetone and in methanol.
mp: 214 °C to 217 °C.

**Coumarin used in gas chromatography**: as prescribed in the monograph on Cassia oil (1496).
The content is not less than 98.0 per cent, calculated by the normalisation procedure.
Cresol. \( \text{C}_7\text{H}_8\text{O} \). (M, 108.1). 1022700. [95-48-7]. \( \alpha \)-Cresol. 2-Methylphenol.

Crystals or a super-cooled liquid becoming dark on exposure to light and air, miscible with ethanol, soluble in about 50 parts of water and soluble in solutions of alkali hydroxides.

\[ d_{20}^0: \text{about } 1.05. \]

\[ n_D^0: \text{1.540 to 1.550.} \]

bp: about 190 °C.

Freezing point (2.2.18): minimum 30.5 °C.

Residue on evaporation: maximum 0.1 per cent m/m, determined by evaporating on a water-bath and drying in an oven at 100-105 °C.

Storage: protected from light, moisture and oxygen.

Distil before use.

\( p \)-Cresol. \( \text{C}_7\text{H}_8\text{O} \). (M, 108.1). 1153100. [106-44-5]. 4-Methylphenol.

Colourless or white or almost white crystals or crystalline mass.

\[ d_{20}^0: \text{about } 1.02. \]

bp: about 202 °C.

\( m \)-Cresol purple. \( \text{C}_9\text{H}_6\text{O}_4\text{S} \). (M, 382.44). 1121700. [2303-01-7]. \( m \)-Cresolsulphonphthalein.

An olive-green, crystalline powder, slightly soluble in water, soluble in alcohol, in glacial acetic acid and in methanol.

\( m \)-Cresol purple solution. 1121701.

Dissolve 0.1 g of \( m \)-cresol purple R in 13 ml of 0.01 M sodium hydroxide, dilute to 100 ml with water R and mix.

Colour change: pH 1.2 (red) to pH 2.8 (yellow); pH 7.4 (yellow) to pH 9.0 (purple).

Cresol red. \( \text{C}_7\text{H}_8\text{O}_3\text{S} \). (M, 382.4). 1022800. [1733-12-6]. Cresolsulphonphthalein. 4,4′-(3H,2,1-Benzoxathiol-3-ylidene)bis(2-methylphenol) S,S-dioxide.

A reddish-brown crystalline powder, slightly soluble in water, soluble in alcohol and in dilute solutions of alkali hydroxides.

Cresol red solution. 1022801.

Dissolve 0.1 g of cresol red R in a mixture of 2.65 ml of 0.1 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R.

Test for sensitivity. A mixture of 0.1 ml of the cresol red solution and 100 ml of carbon dioxide-free water R to which 0.15 ml of 0.02 M sodium hydroxide has been added is purple-red. Not more than 0.15 ml of 0.02 M hydrochloric acid is required to change the colour to yellow.

Colour change: pH 7.0 (yellow) to pH 8.6 (red).

Crystal violet. \( \text{C}_9\text{H}_6\text{ClN}_3 \). (M, 408.0). 1022900. [548-62-9].

Schultz No. 78.

Colour Index No. 42555.

Hexamethyl-pararosaniline chloride.

Dark-green powder or crystals, soluble in water and in alcohol.

Crystal violet solution. 1022901.

Dissolve 0.5 g of crystal violet R in anhydrous acetic acid R and dilute to 100 ml with the same solvent.

Test for sensitivity. To 50 ml of anhydrous acetic acid R add 0.1 ml of the crystal violet solution. On addition of 0.1 ml of 0.1 M perchloric acid the bluish-purple solution turns bluish-green.

Cupric chloride. \( \text{CuCl}_2\cdot\text{H}_2\text{O} \). (M, 170.5). 1023000. [10125-13-0]. Cupric chloride dihydrate.

Greenish-blue powder or crystals, deliquescent in moist air, efflorescent in dry air, freely soluble in water, in alcohol and in methanol, sparingly soluble in acetone.

Storage: in an airtight container.

Cupri-citric solution. 1023100.

Dissolve 25 g of copper sulphate R, 50 g of citric acid R and 144 g of anhydrous sodium carbonate R in water R and dilute to 1000 ml with the same solvent.

Cupri-citric solution R1. 1023200.

Dissolve 25 g of copper sulphate R, 50 g of citric acid R and 144 g of anhydrous sodium carbonate R in water R and dilute to 1000 ml with the same solvent.

Adjust the solution so that it complies with the following requirements.

a) To 25.0 ml add 3 g of potassium iodide R. Add 25 ml of a 25 per cent m/m solution of sulphuric acid R with precaution and in small quantities. Titrate with 0.1 M sodium thiosulphate using 0.5 ml of starch solution R, added towards the end of the titration, as indicator.

24.5 ml to 25.5 ml of 0.1 M sodium thiosulphate is used in the titration.

b) Dilute 10.0 ml to 100.0 ml with water R and mix. To 10.0 ml of the solution, add 25.0 ml of 0.1 M hydrochloric acid and heat for 1 h on a water-bath. Cool, adjust with water R to the initial volume and titrate with 0.1 M sodium hydroxide, using 0.1 ml of phenolphthalein solution R1 as indicator.

5.7 ml to 6.3 ml of 0.1 M sodium hydroxide is used in the titration.

c) Dilute 10.0 ml to 100.0 ml with water R and mix. Titrate 10.0 ml of the solution with 0.1 M hydrochloric acid, using 0.1 ml of phenolphthalein solution R1 as indicator.

6.0 ml to 7.5 ml of 0.1 M hydrochloric acid is used in the titration.

Cupriethylene diamine hydroxide solution. 3008700. [14552-35-3].

The molar ratio of ethylenediamine to copper is 2.00 ± 0.04.

This solution is commercially available.

Cupri-tartaric solution. 1023300.

Solution I. Dissolve 34.6 g of copper sulphate R in water R and dilute to 500 ml with the same solvent.

Solution II. Dissolve 173.0 g of sodium potassium tartrate R and 50 g of sodium hydroxide R in 400 ml of water R. Heat to boiling, allow to cool and dilute to 500 ml with carbon dioxide-free water R.

Mix equal volumes of the 2 solutions immediately before use.

Cupri-tartaric solution R2. 1023302.

Add 1 ml of a solution containing 5 g/l of copper sulphate R and 10 g/l of potassium tartrate R to 50 ml of sodium carbonate solution R1. Prepare immediately before use.

Cupri-tartaric solution R3. 1023303.

Prepare a solution containing 10 g/l of copper sulphate R and 20 g/l of sodium tartrate R. To 1.0 ml of the solution add 50 ml of sodium carbonate solution R2. Prepare immediately before use.

Cupri-tartaric solution R4. 1023304.

Solution I. 150 g/l copper sulphate R.
**Solution II.** Dissolve 2.5 g of anhydrous sodium carbonate R, 2.5 g of potassium sodium tartrate R, 2.0 g of sodium hydrogen carbonate R, and 20.0 g of anhydrous sodium sulphate R in water R and dilute to 100 ml with the same solvent.

Mix 1 part of solution I with 25 parts of solution II immediately before use.

**Curcumin.** \(\text{C}_{15}\text{H}_{22}\text{O}_{6}\) (M 368.4). 1023500. [458:37-7]. 1,7-bis(4-Hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione.

An orange-brown, crystalline powder, practically insoluble in water, soluble in glacial acetic acid.

mp: about 183 °C.

**Cyclohexylamine.** \(\text{C}_7\text{H}_8\text{N}\) (M 102). 1023901. 1024000. [108-91-8].

A colourless liquid, soluble in water, miscible with usual organic solvents.

\(n_d^2\): about 1.460.

bp: 134 °C to 135 °C.

**Cyclohexanedinitritol tetra-acetic acid.** \(\text{C}_8\text{H}_8\text{N}_2\text{O}_8\cdot \text{H}_2\text{O}\) (M 364.4). 1024100. trans-Cyclohexylene-1,2-dinitrilo-N,N,N',N'-tetracetic acid.

A white or almost white, crystalline powder.

mp: about 204 °C.

**Cyclohexymethanol.** \(\text{C}_7\text{H}_14\text{O}\) (M 111). 1135000. [372-09-8].

A liquid with a slight odour of camphor, soluble in alcohol.

\(n_d^2\): about 1.464.

bp: about 185 °C.

**3-Cyclohexylpropionic acid.** \(\text{C}_9\text{H}_{12}\text{O}_2\) (M 156.2). 1119200. [701-97-3].

A clear liquid.

\(d_2^0\): about 0.998.

\(n_d^2\): about 1.4648.

bp: about 130 °C.

**Cyhalothrin.** \(\text{C}_{23}\text{H}_{19}\text{ClF}_3\text{NO}_3\) (M 449.9). 1125000. [91465-08-6].

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

**p-Cymene.** \(\text{C}_{10}\text{H}_{14}\) (M 134.2). 1113400. [99-87-6].

1-Isopropyl-4-methylbenzene.

A colourless liquid, practically insoluble in water, soluble in alcohol.

\(d_2^0\): about 0.858.

\(n_d^2\): about 1.4895.

bp: 175 °C to 178 °C.

**Peppermint oil.**

**Test solution.** Examine by gas chromatography (2.2.28) as prescribed in the monograph Peppermint oil (0405).

**Cinnamyl alcohol.** \(\text{C}_{17}\text{H}_{20}\text{O}\) (M 256). 1024300. [7094-33-9].

A white amorphous mass, odourless.

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**Cinnamyl alcohol.** \(\text{C}_{17}\text{H}_{20}\text{O}\) (M 256). 1024300. [7094-33-9].

A white amorphous mass, odourless.
l-Cystine. \( \text{C}_{4} \text{H}_{11} \text{N}_{2} \text{O}_{5} \text{S}_{2} \) (\( M \), 240.3). \text{1024400.} \ [56-89-3].

A white or almost white, crystalline powder, practically insoluble in water and in alcohol. It dissolves in dilute solutions of alkali hydroxides. It decomposes at 250 °C.

\[ [\alpha]_{D}^{20} : -218 \text{ to } -224, \text{ determined in 1 M hydrochloric acid.} \]

Cytosine. \( \text{C}_{4} \text{H}_{9} \text{N}_{4} \text{O}_{2} \) (\( M \), 111.1). \text{1160800.} \ [71-30-7].

Content: minimum 95.0 per cent.

Dantron. \( \text{C}_{10} \text{H}_{10} \text{O}_{5} \) (\( M \), 240.2). \text{1024500.} \ [117-10-2].

1,8-Dihydroxyanthraquinone. 1,8-Dihydroxyanthracene-9, 10-dione.

A crystalline orange powder, practically insoluble in water, slightly soluble in alcohol, soluable in solutions of alkali hydroxides.

mp: about 195 °C.

Dantron used in the sesquiterpenic acids assay in Valerian root (0453) complies with the following additional requirements.

\[ A_{1}^{\text{cm}} : 355 \text{ to } 375, \text{ determined in } 1 \text{ M potassium hydroxide.} \]

Assay. Examine by liquid chromatography (2.2.29) as prescribed in the monograph on Valerian Root (0453) at the concentration of the reference solution. The content of dantron is not less than 95 per cent calculated by the normalisation procedure.

\( o,p'\text{-DDT.} \ \text{C}_{14} \text{H}_{11} \text{Cl}_{4} \) (\( M \), 320.0). \text{1125200.} \ [53-19-0].

1-(2-Chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethane.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

bp: about 300 °C.

Decanal. \( \text{C}_{10} \text{H}_{20} \) (\( M \), 158.3). \text{1024700.} \ [112-30-1]. n-Decyl alcohol.

A colourless liquid, practically insoluble in water.

\[ n_{D}^{20} : \text{about } 1.411. \]

bp: about 174 °C.

Decanol. \( \text{C}_{10} \text{H}_{22} \) (\( M \), 142.3). \text{1024600.} \ [124-18-5].

A colourless liquid, practically insoluble in water.

\[ n_{D}^{20} : \text{about } 1.436. \]

bp: about 230 °C.

Deltamethrin. \( \text{C}_{22} \text{H}_{16} \text{Br}_{2} \text{NO}_{3} \) (\( M \), 505.2). \text{1125800.} \ [52918-63-5].

bp: about 300 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Demeclocycline hydrochloride. \text{1145600.}

See Demeclocycline hydrochloride (0176).

Demethylfumazenil. \( \text{C}_{14} \text{H}_{10} \text{F}_{2} \text{N}_{3} \text{O}_{3} \) (\( M \), 289.3). \text{1149300.} \ [79089-72-8].

Ethy 8-fluoro-6-oxo-5,6-dihydro-4H-pyrimidine-2,4-dione.

mp: about 98 °C.

2′-Deoxy-d-ribose. \( \text{C}_{3} \text{H}_{6} \text{O}_{5} \) (\( M \), 134.1). \text{1163900.} \ [533-67-5].

Thyminose. 2-Deoxy-d-erythro-pentofuranosyl-1,5,6-dihydro-4H-pyrimidine-2,4-dione.

mp: about 207 °C to 209 °C.

Deuterated acetone. \( \text{C}_{3} \text{H}_{6} \text{O} \) (\( M \), 64.1). \text{1024900.} \ [666-52-4].

Acetone-d_{6}. \ (\text{d}_{6})-Acetone.

The degree of deuteration is not less than 99.5 per cent.

Content: not less than 99.5 per cent.

bp: 190 °C to 191 °C.

Decanal used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Sweet orange oil (1811). The content is not less than 99 per cent, calculated by the normalisation procedure.

Decane. \( \text{C}_{10} \text{H}_{22} \) (\( M \), 142.3). \text{1024600.} \ [124-18-5].

A colourless liquid, practically insoluble in water.

\[ n_{D}^{20} : \text{about } 1.411. \]

bp: about 174 °C.

Decanol. \( \text{C}_{10} \text{H}_{22} \) (\( M \), 158.3). \text{1024700.} \ [112-30-1]. n-Decyl alcohol.

A viscous liquid, solidifying at about 6 °C, practically insoluble in water, soluble in alcohol.

\[ n_{D}^{20} : \text{about } 1.436. \]

bp: about 230 °C.

Deltamethrin. \( \text{C}_{22} \text{H}_{16} \text{Br}_{2} \text{NO}_{3} \) (\( M \), 505.2). \text{1125800.} \ [52918-63-5].

bp: about 300 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Deltamethrin.

2′-Deoxy-d-ribose. \( \text{C}_{3} \text{H}_{6} \text{O}_{5} \) (\( M \), 134.1). \text{1163900.} \ [533-67-5].

Thyminose. 2-Deoxy-d-erythro-pentofuranosyl-1,5,6-dihydro-4H-pyrimidine-2,4-dione.

mp: about 180 °C.

Chromatography. Examine as prescribed in the monograph on Idoxuridine (0669), applying 5 µl of a 0.25 g/l solution. The chromatogram obtained shows only one principal spot.

Destaining solution. \text{1012202.}

A mixture consisting of 1 volume of glacial acetic acid \( R \), 4 volumes of methanol \( R \) and 5 volumes of water \( R \).

Deuterated acetic acid. \( \text{C}_{2} \text{H}_{4} \text{O}_{2} \) (\( M \), 64.1). \text{1101100.} \ [1186-52-3].

Tetradecanoic acid. Acetic-d_{12} acid-d.

The degree of deuteration is not less than 99.7 per cent.

\[ \delta_{D}^{20} : \text{about } 1.12. \]

\[ n_{D}^{20} : \text{about } 1.368. \]

bp: about 115 °C.

mp: about 16 °C.

Deuterated acetone. \( \text{C}_{3} \text{H}_{6} \text{O} \) (\( M \), 64.1). \text{1024900.} \ [666-52-4].

Acetone-d_{6}. \ (\text{d}_{6})-Acetone.

The degree of deuteration is not less than 99.5 per cent.

A clear, colourless liquid, miscible with water, with dimethylformamide, with ethanol and with methanol.

\[ \delta_{D}^{20} : \text{about } 0.87. \]
4.1.1. Reagents

Deuterated chloroform. C\textsubscript{2}H\textsubscript{2}Cl\textsubscript{2}. (\textit{M}, 120.4). 1025000. [865-49-6]. (\textit{H})-Chloroform. Chloroform-d.<ref>
The degree of deuteration is not less than 99.7 per cent.

A clear, colourless liquid, practically insoluble in water, miscible with acetone and with alcohol. It may be stabilised over silver foil.

\textit{bp}: about 55 °C.

Water and deuterium oxide. Not more than 0.1 per cent.

Deuterated dimethyl sulphoxide. C\textsubscript{2}H\textsubscript{4}OS. (\textit{M}, 84.2). 1025200. [811-98-3]. (\textit{H})-Dimethyl sulphoxide. Dimethyl sulphoxide-d.<ref>
The degree of deuteration is not less than 99.8 per cent.

A very hygroscopic liquid, practically colourless, viscous, soluble in water, in acetone and in ethanol.

\textit{d}\textsubscript{20}\textsuperscript{0}: about 1.18.

\textit{mp}: about 20 °C.

Water and deuterium oxide: maximum 0.05 per cent.

Deuterated methanol. C\textsubscript{2}H\textsubscript{4}O. (\textit{M}, 46). 1025300. [811-98-3]. (\textit{H})-Methanol. Methanol-d.<ref>
The degree of deuteration is not less than 99.8 per cent.

Clear, colourless liquid miscible with water, with alcohol and with methylene chloride.

\textit{d}\textsubscript{20}\textsuperscript{0}: about 0.888.

\textit{n}\textsubscript{D}: about 1.326.

\textit{bp}: 65.4 °C.


The degree of deuteration is not less than 99.7 per cent.

\textit{d}\textsubscript{20}\textsuperscript{0}: about 1.11.

\textit{n}\textsubscript{D}: about 1.328.

\textit{bp}: about 101 °C.


The degree of deuteration is not less than 99.95 per cent.

Developer solution. 1122500.

Dilute 2.5 ml of a 20 g/l solution of citric acid R and 0.27 ml of formaldehyde R to 500.0 ml with water R.

Dextran for chromatography, cross-linked R2. 1025500.

A bead-form dextran with a fraction range suitable for the separation of peptides and proteins with relative molecular masses of 15 \times 10\textsuperscript{3} to 30 \times 10\textsuperscript{3}. When dry, the beads have a diameter of 20 μm to 80 μm.

Dextran for chromatography, cross-linked R3. 1025600.

A bead-form dextran with a fraction range suitable for the separation of peptides and proteins with relative molecular masses of 4 \times 10\textsuperscript{3} to 15 \times 10\textsuperscript{3}. When dry, the beads have a diameter of 40 μm to 120 μm.

Dextrose. 1025700. [50-99-7]. See glucose R.

3,3'-Diaminobenzidine tetrahydrochloride. C\textsubscript{12}H\textsubscript{18}Cl\textsubscript{4}N\textsubscript{4}2H\textsubscript{2}O. (\textit{M}, 396.1). 1098000. [7411-49-6]. 3,3',4,4'-Biphenyl-tetramine.

An almost white or slightly pink powder, soluble in water.

\textit{mp}: about 280 °C, with decomposition.

Diammonium 2,2'-azinobis(3-ethylbenzothiazoline-6-sulphonate). C\textsubscript{18}H\textsubscript{14}N\textsubscript{4}O\textsubscript{8}S\textsubscript{4}. (\textit{M}, 548.7). 1135000. [30931-67-0]. ABTS. Diammonium 2,2'-diazanediylidine-bis[3-ethyl-2,3-dihydrobenzothiazole-6-sulphonate].

Chromogenic substrate suitable for use in ELISA procedures.

Green tablets, freely soluble in water.

pH (2.2.3): 4.2 to 5.8 for a 0.1 g/l solution.

Diatomaceous earth. 1025900. [91053-39-3].

A white or almost white, fine granular powder, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in alcohol.

The substance may be identified by microscopic examination with a magnification of × 500.

Diatomaceous earth for gas chromatography. 1026000.

A white or almost white, fine granular powder, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in alcohol.

The substance may be identified by microscopic examination with a magnification of × 500.

Diatomaceous earth for gas chromatography R1. 1026100.

A white or almost white, fine granular powder, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in alcohol.

The substance may be identified by microscopic examination with a magnification of × 500.

Diatomaceous earth for gas chromatography R2. 1026200.

A white or almost white, fine granular powder with a specific surface area of about 0.5 m\textsuperscript{2}/g, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in alcohol.

The substance may be identified by microscopic examination with a magnification of × 500.

Diatomaceous earth for gas chromatography, silanised. 1026300.

Diatomaceous earth for gas chromatography R1 silanised with dimethyldichlorosilane or other suitable silanising agents.

Diatomaceous earth for gas chromatography, silanised R1. 1026400.

Prepared from crushed pink firebrick and silanised with dimethyldichlorosilane or other suitable silanising agents.

The substance is purified by treating with hydrochloric acid R and washing with water R.

Particle size. Not more than 5 per cent is retained on a sieve No. 180. Not more than 10 per cent passes a sieve No. 125.
Diazinon. C₁₁H₁₉N₂O₂PS. (M, 304.3). 1125900. [333-41-5].
A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Diazobenzensulphonic acid solution R1. 1026500.
Dissolve 0.9 g of sulphanilic acid R in a mixture of 30 ml of dilute hydrochloric acid R and 70 ml of water R. To 3 ml of the solution add 3 ml of a 50 g/l solution of sodium nitrite R. Cool in an ice-bath for 5 min, add 12 ml of the sodium nitrite solution and cool again. Dilute to 100 ml with water R and keep the reagent in an ice-bath. Prepare extemporaneously but allow to stand for 15 min before use.

N-Butylbutan-1-amine.

Dibutylammonium phosphate for ion-pairing. 1168800.
A colourless solution of 10 per cent to 15 per cent V/V of di-n-butylamine and 12 per cent to 17 per cent V/V of phosphoric acid in water, suitable for ion-pairing in liquid chromatography.

Dibutyl ether. C₈H₁₈O. (M, 130.2). 1026700. [142-96-1].
A colourless, flammable liquid, practically insoluble in water, miscible with ethanol.

Dichloroacetic acid. C₂H₂Cl₂O₂. (M, 102.7). 1027000.

Dichloroacetic acid solution. 1027001.
Dilute 67 ml of dichloroacetic acid R to 300 ml with water R and neutralise to blue litmus paper R using ammonia R. Cool, add 33 ml of dichloroacetic acid R and dilute to 600 ml with water R.

Dichlorobenzene. C₆H₅Cl₂. (M, 147.0). 1027100. [95-50-1].
1,2-Dichlorobenzene.
A colourless, oily liquid, practically insoluble in water, soluble in ethanol.
d₂₀ : about 1.31.
bp: about 180 °C.

2,3-Dichloro-5,6-dicynanobenzoquinone. C₂₀H₁₈Cl₂N₂O₂. (M, 421.2). 1126100. [84-58-2]. 4,5-Dichloro-2,3-dioxo-cyclohexa-1,4-diene-1,2-dicarbonitrile.
Yellow or orange crystals, soluble in dioxan and in acetic acid, slightly soluble in methylene chloride. It decomposes in water.

Dichloroerufluorescein. C₂₀H₁₆Cl₂O₁₂. (M, 401.2). 1027200. [76-54-0]. 2,7-Dichlorofluorescein.
2-(2,7-Dichloro-6-hydroxy-3-oxo-3-oxo-2,6-dihydroxy-3H-xanthen-9-yl)benzoic acid.
A yellow-brown to yellow-orange powder, slightly soluble in water, freely soluble in alcohol and in dilute solutions of alkali hydroxides giving a solution showing a yellowish-green fluorescence.

Dichlorophenolindophenol, sodium salt. C₁₂H₁₀BrClN₂O₂. (M, 414.1). 1142600. [113310-88-6].
White or almost white, crystalline powder.

Dichlorophenolindophenol standard solution. 1027301.
Dissolve 50.0 mg of dichlorophenolindophenol, sodium salt R in 100.0 ml of water R and filter.

Standardisation. Dissolve 20.0 mg of ascorbic acid R in 10 ml of a freshly prepared 200 g/l solution of metaphosphoric acid R and dilute to 250.0 ml with water R. Titrate 5.0 ml rapidly with the dichloro-phenolindophenol solution standard, added from a microburette graduated in 0.01 ml, until the pink colour persists for 10 s, the titration occupying not more than 2 min. Dilute the dichloro-phenolindophenol solution with water R to make 1 ml of the solution equivalent to 0.1 mg of ascorbic acid (C₆H₈O₆).

Storage: use within 3 days.

Dichlorophenolindophenol standard solution. 1027301.
Dissolve 50.0 mg of dichlorophenolindophenol, sodium salt R in 100.0 ml of water R and filter.

Standardisation. Dissolve 20.0 mg of ascorbic acid R in 10 ml of a freshly prepared 200 g/l solution of metaphosphoric acid R and dilute to 250.0 ml with water R. Titrate 5.0 ml rapidly with the dichloro-phenolindophenol standard solution, added from a microburette graduated in 0.01 ml, until the pink colour persists for 10 s, the titration occupying not more than 2 min. Dilute the dichloro-phenolindophenol solution with water R to make 1 ml of the solution equivalent to 0.1 mg of ascorbic acid (C₆H₈O₆).

Storage: use within 3 days.

Dichlorphenolindophenol standard solution. 1027301.
Dissolve 50.0 mg of dichlorophenolindophenol, sodium salt R in 100.0 ml of water R and filter.

Standardisation. Dissolve 20.0 mg of ascorbic acid R in 10 ml of a freshly prepared 200 g/l solution of metaphosphoric acid R and dilute to 250.0 ml with water R. Titrate 5.0 ml rapidly with the dichloro-phenolindophenol standard solution, added from a microburette graduated in 0.01 ml, until the pink colour persists for 10 s, the titration occupying not more than 2 min. Dilute the dichloro-phenolindophenol solution with water R to make 1 ml of the solution equivalent to 0.1 mg of ascorbic acid (C₆H₈O₆).

Storage: use within 3 days.

Dichlorphenolindophenol standard solution. 1027301.

| Test solution (a). Dissolve 5.00 g of the substance to be examined in acetonitrile R and dilute to 10.0 ml with the same solvent.
| Test solution (b). Dissolve 5.00 g of the substance to be examined in acetonitrile R, add 1.0 ml of the internal standard solution and dilute to 10.0 ml with the same solvent.
| Reference solutions. Dissolve 0.50 g of ethanamine R in acetonitrile R and dilute to 10.0 ml with the same solvent. To 0.5 ml, 1.0 ml and 2.0 ml of this solution, add 1.0 ml of the internal standard solution and dilute to 10.0 ml with acetonitrile R.
| The chromatographic procedure may be carried out using:
| — a column 1 m long and 4 mm internal diameter packed with diphenylphénylène oxide polymer R (180 µm to 250 µm),
| — nitrogen for chromatography R as the carrier gas at a flow rate of 40 ml/min,
| — a flame-ionisation detector.

Maintain the temperature of the column at 125 °C for 3 min and then raise to 300 °C at a rate of 12 °C/min. Maintain the temperature of the injection port at 250 °C and that of the detector at 280 °C. Inject 1.0 µl of each test solution and 1.0 µl of each reference solution.

Storage: in an airtight container.


A clear, colourless or slightly yellowish liquid, practically insoluble in water, soluble in alcohol and in most other organic solvents.

bp: about 105 °C. 
mp: about 0.98.
\( \eta_1^20 \): about 1.418.


A white or almost white, crystalline powder.

mp: about 232 °C.


A white or almost white, crystalline powder.

mp: about 181 °C.


A white or almost white, crystalline powder.

mp: about 1.09.


A pale yellow or greenish-yellow crystalline powder, practically insoluble in water, soluble in alcohol and in dilute alkaline solutions.

A suitable certified reference solution (10 ng/ml in cyclohexane) may be used.

A suitable certified reference solution (10 ng/ml in cyclohexane) may be used.

A white or almost white, crystalline powder, practically insoluble in water, freely soluble in acetone and in light petroleum, slightly soluble in alcohol.

mp: about 39 °C.


A white or almost white, crystalline powder, practically insoluble in water, soluble in alcohol and in most other organic solvents.

bp: about 227 °C.

mp: about 4 °C.


Colourless or brownish-yellow liquid, soluble in water, freely soluble in acetone and in light petroleum, slightly soluble in alcohol.

bp: about 38 °C.

mp: about 176 °C.


A white or almost white, crystalline powder, practically insoluble in water, soluble in alcohol and in most other organic solvents.

A suitable certified reference solution (10 ng/ml in cyclohexane) may be used.

A white or almost white, crystalline powder, practically insoluble in water, freely soluble in acetone and in light petroleum, slightly soluble in alcohol.

mp: about 39 °C.


mp: about 176 °C.

A suitable certified reference solution (10 ng/ml in cyclohexane) may be used.


A viscous, clear, slightly yellow liquid or deliquescent crystals melting at about 28 °C, very soluble in water, in acetone and in methanol.

\( \eta_1^20 \): about 0.98.

Diethanolamine used in the test for alkaline phosphatase complies with the following additional test.

**Ethanolamine**: maximum 1.0 per cent. Examine by gas chromatography (2.2.28), using 3-amino-1-propanol R as the internal standard.

**Internal standard solution.** Dissolve 1.00 g of 3-amino-1-propanol R in acetone R and dilute to 10.0 ml with the same solvent.
A slightly oily liquid, colourless or slightly yellow, strong odour of ammonia, irritant to the skin, eyes and mucous membranes. 
d_{20}^0: 0.827.  
bp: 145 °C to 147 °C.  
Water (2.5.12): maximum 1.0 per cent, determined on 0.500 g.  

Di(2-ethylphyl) phthalate.  C_{12}H_{14}O.  (M, 162.0).  1028100.  
Di(2-ethylhexyl) benzene-1,2-dicarboxylate.  
A colourless, oily liquid, practically insoluble in water, soluble in organic solvents.  
d_{20}^0: about 0.98.  
ν_{20}^0: about 1.486.  
Viscosity (2.2.9): about 80 mPas.  

Diethylphenylenediamine sulphate.  C_{10}H_{18}N_{2}O_{4}S.  [7764-50-3].  

Assay with the following additional test.  
Dihydrocarvone used in gas chromatography complies with most organic solvents.  
A slightly oily liquid, colourless or slightly yellow, strong odour of ammonia, irritant to the skin, eyes and mucous membranes.  
d_{20}^0: 0.723 to 0.728.  
bp: 67 °C to 69 °C.  
Do not distil if the di-isopropyl ether does not comply with the test for peroxides.  
Peroxides.  Place 8 ml of potassium iodide and starch solution R in a 12 ml ground-glass-stoppered cylinder about 1.5 cm in diameter.  Fill completely with the substance to be examined, shake vigorously and allow to stand protected from light for 30 min.  No colour is produced.  

Storage: protected from light and heat until decolorised.  

Diethylenetriamine.  C_{12}H_{17}N_{3}O.  (M, 189.2).  1148300.  

Dihydrocapsaicin.  C_{18}H_{29}NO_{3}.  (M, 295.4).  1028700.  

See Digitoxin (0078).  

Dihydroxycapric acid.  C_{9}H_{17}O_{5}.  (M, 154.1).  1148200.  

Light yellow crystals.  

mp: about 200 °C.  

5,7-Dihydroxy-4-methylcoumarin.  C_{17}H_{14}O.  (M, 212.2).  1149400.  
[2107-76-8].  5,7-Dihydroxy-4-methyl-2H-1-benzopyran-2-one.  

Light yellowish powder, practically insoluble in water, sparingly soluble in alcohol.  
mp: 295 °C to 303 °C.  

Dihydroxyphthalic acid.  1029000.  [132-86-5].  
See 1,3-dihydroxyphthalic acid R.  

1,3-Dihydroxynaphthalene.  C_{10}H_{8}O.  (M, 160.2).  1029000.  
[132-86-5].  Naphthalene-1,3-diol.  
A crystalline, generally brownish-violet powder, freely soluble in water and in alcohol.  
mp: about 125 °C.  

2,7-Dihydroxynaphthalene.  C_{10}H_{8}O.  (M, 160.2).  1029100.  [582-17-2].  Naphthalene-2,7-diol.  
Needles, soluble in water and in alcohol.  
mp: about 190 °C.  

2,7-Dihydroxynaphthalene solution.  1029101.  
Dissolve 10 mg of 2,7-dihydroxynaphthalene R in 100 ml of sulphuric acid R and allow to stand until decolorised.  
Storage: use within 2 days.  

5,7-Diiodoquinolin-8-ol.  C_{9}H_{14}I_{2}O.  (M, 397.0).  1157100.  
[83-73-8].  5,7-Diiodooxine.  
Yellowish-brown powder, sparingly soluble in acetone and in ethanol (96 per cent).  

Content: minimum 95.0 per cent of C_{9}H_{14}I_{2}O.  

Diisobutyl ketone.  C_{10}H_{20}O.  (M, 142.2).  1029200.  [108-83-8].  

A clear, colourless liquid, slightly soluble in water, miscible with most organic solvents.  
ν_{20}^0: about 1.414.  
bp: about 168 °C.  

Diisopropyl ether.  C_{6}H_{14}O.  (M, 102.2).  1029300.  [108-20-3].  

A clear, colourless liquid, very slightly soluble in water, miscible with alcohol.  
d_{20}^0: 0.792.  
bp: 140 °C to 145 °C.  

Diethylbenzene-1,4-dicarboxylate.  
A white or slightly yellow powder, soluble in water.  
mp: about 185 °C, with decomposition.  

Storage: protected from light.  

Digitoxin.  C_{37}H_{48}O_{12}.  (M, 1229).  1028700.  [11024-24-1].  
3β-[4β-Clucopyranosyl-(1→3)-Oβ-galactopyranosyl-(1→2)-Oβ-sucrospyranosyl-(1→4)-Oβ-α-spirostan-2α, 15β-diol.  

Crystals, practically insoluble in water, sparingly soluble in ethanol, slightly soluble in alcohol.  

Digitoxin solution.  1028800.  [71-63-6].  
See Digitoxin (0078).  

Diiodoquinolin-8-ol.  C_{9}H_{14}I_{2}O.  (M, 397.0).  1157100.  
[83-73-8].  5,7-Diiodooxine.  
Yellowish-brown powder, sparingly soluble in acetone and in ethanol (96 per cent).  

Content: minimum 95.0 per cent of C_{9}H_{14}I_{2}O.  

Diisobutyl ketone.  C_{10}H_{20}O.  (M, 142.2).  1029200.  [108-83-8].  

A clear, colourless liquid, slightly soluble in water, miscible with most organic solvents.  
ν_{20}^0: about 1.414.  
bp: about 168 °C.  

Diisopropyl ether.  C_{6}H_{14}O.  (M, 102.2).  1029300.  [108-20-3].  

A clear, colourless liquid, very slightly soluble in water, miscible with alcohol.  
d_{20}^0: 0.792.  
bp: 140 °C to 145 °C.  

Do not distil if the di-isopropyl ether does not comply with the test for peroxides.  
Peroxides.  Place 8 ml of potassium iodide and starch solution R in a 12 ml ground-glass-stoppered cylinder about 1.5 cm in diameter.  Fill completely with the substance to be examined, shake vigorously and allow to stand protected from light for 30 min.  No colour is produced.  

The name and concentration of any added stabiliser are stated on the label.  

Storage: protected from light.
4,4′-Dimethoxybenzophenone. C_{14}H_{10}O_{2}. (M, 242.3). 1126300. [90-96-0]. bis(4-Methoxyphenyl)methanone.

A white or almost white powder, practically insoluble in water and slightly soluble in alcohol.

mp: about 142 °C.

Dimethoxypropane. C_{12}H_{22}O_{2}. (M, 104.1). 1105200. [77-76-9]. 2,2-Dimethoxypropane.

A colourless liquid, decomposing on exposure to moist air.

\( d_{20}^0 \): about 0.847.

\( n_D^0 \): about 1.378.

bp: about 83 °C.

Dimethylacetamide. C_{6}H_{11}NO. (M, 87.1). 1029700. [127-19-5]. N,N-Dimethylacetamide.

Content: minimum 99.5 per cent of C_{6}H_{11}NO.

mp: about 92.2 °C.

bp: about 102 °C.

Dimethylamine. C_{3}H_{7}N. (M, 45.08). 1168900. [124-40-3]. N-methylmethanamine.

Colourless, flammable gas.

bp: about 7 °C.

mp: about –92.2 °C.

**Dimethylamine solution.** 1168901.

A 40% g/1 solution.

Clear, colourless solution.

Density: about 0.89.

bp: about 54 °C.

mp: about –37 °C.

Dimethylaminobenzaldehyde. C_{9}H_{11}NO. (M, 149.2). 1029800. [100-10-7]. 4-Dimethylaminobenzaldehyde.

White or yellowish-white crystals, soluble in alcohol and in dilute acids.

mp: about 74 °C.

Dimethylaminobenzaldehyde solution R1. 1029801.

Dissolve 0.2 g of dimethylaminobenzaldehyde R in 20 ml of alcohol R and add 0.5 ml of hydrochloric acid R.

Shake the solution with activated charcoal R and filter. The colour of the reagent is less intense than that of iodic acid solution R3. Prepare immediately before use.

Dimethylaminobenzaldehyde solution R2. 1029802.

Dissolve 0.2 g of dimethylaminobenzaldehyde R, without heating, in a mixture of 4.5 ml of water R and 5.5 ml of hydrochloric acid R. Prepare immediately before use.

Dimethylaminobenzaldehyde solution R6. 1029803.

Dissolve 0.125 g of dimethylaminobenzaldehyde R in a cooled mixture of 35 ml of water R and 65 ml of sulphuric acid R. Add 0.1 ml of a 50 g/1 solution of ferric chloride R. Before use allow to stand for 24 h, protected from light.

Storage: when stored at room temperature it must be used within 1 week; when kept in a refrigerator, it may be stored for several months.

Dimethylaminobenzaldehyde solution R7. 1029804.

Dissolve 1.0 g of dimethylaminobenzaldehyde R in 50 ml of hydrochloric acid R and add 50 ml of alcohol R.

Storage: protected from light; use within 4 weeks.

**Dimethylaminobenzaldehyde solution R8.** 1029805.

Dissolve 0.25 g of dimethylaminobenzaldehyde R in a mixture of 5 g of phosphoric acid R, 45 g of water R and 50 g of anhydrous acetic acid R. Prepare immediately before use.

4-Dimethylaminocinnamaldehyde. C_{11}H_{15}NO. (M, 175.2). 1029900. [6203-18-5]. 3-(4-Dimethylamino phenyl)prop-2-enal.

Orange to orange-brown crystals or powder. Sensitive to light.

mp: about 138 °C.

4-Dimethylaminocinnamaldehyde solution. 1029901.

Dissolve 2 g of 4-dimethylaminocinnamaldehyde R in a mixture of 100 ml of hydrochloric acid R1 and 100 ml of ethanol R. Dilute the solution to four times its volume with ethanol R immediately before use.

2-(Dimethylamino)ethyl methacrylate. C_{9}H_{14}NO_{2}. (M, 157.2). 1147200. [2867-47-2]. 2-(Dimethylamino)ethyl 2-methylpropenoate.

\( d_20^0 \): about 0.930.

bp: about 187 °C.

Dimethylaminonaphthalenesulphonyl chloride. C_{13}H_{14}ClNO_{2}S. (M, 269.8). 1030000. [605-65-2]. 5-Dimethyl-amino-1-naphthalenesulphonyl chloride.

A yellow, crystalline powder, slightly soluble in water, soluble in methanol.

mp: about 70 °C.

3-Dimethylaminophenol. C_{6}H_{11}NO. (M, 137.2). 1156500. [99-07-0]. 3-(Dimethylamino)phenol.

Grey powder, slightly soluble in water.

mp: about 80 °C.

Dimethylaniline. C_{8}H_{11}N. (M, 121.2). 1030100. [121-69-7]. N,N-Dimethylaniline.

A clear, oily liquid, almost colourless when freshly distilled, darkening on storage to reddish-brown, practically insoluble in water, freely soluble in alcohol.

\( n_D^0 \): about 1.558.

**Distillation range (2.2.11).** Not less than 95 per cent distils between 192 °C and 194 °C.

**N,N-Dimethylaniline.** 1030100. [121-69-7].

See Dimethylaniline R.

2,3-Dimethylaniline. C_{8}H_{12}ClN. (M, 121.2). 1105300. [87-59-2]. 2,3-Xylidine.

A yellowish liquid, sparingly soluble in water, soluble in alcohol.

\( d_20^0 \): 0.993 to 0.995.

\( n_D^0 \): about 1.569.

bp: about 224 °C.

2,6-Dimethylaniline. C_{8}H_{12}ClN. (M, 121.2). 1030200. [87-62-7]. 2,6-Xylidine.

A colourless liquid, sparingly soluble in water, soluble in alcohol.

\( d_20^0 \): about 0.98.

2,6-Dimethylaniline hydrochloride. C_{8}H_{12}ClN. (M, 157.6). 1169000. [21436-98-6]. 2,6-Dimethylaniline hydrochloride.

Content: minimum 98.0 per cent.
2,4-Dimethyl-6-tert-butylphenol. C_{12}H_{16}O. (M, 178.3). 1126500. [187909-0].

Dimethyl carbonate. C_{4}H_{8}O_{2}. (M, 90.1). 1119300. [616-38-6]. Carbonic acid dimethyl ester. Liquid, insoluble in water, miscible with alcohol.

1,1-Dimethylethylamine. C_{4}H_{11}N. (M, 73.1). 1100900. [1120-24-7]. N,N-Dimethylethylamine.

Dimethyl-β-cyclodextrin. C_{6}H_{14}O_{6}. (M, 1331). 1169100. [5116-71-3]. Heptakis(2,6-di-O-methyl)cyclomaltoheptaose. Cycloheptakis(1,4,2,6-di-O-methyl-α-D-glucopyranosyl). 2,2′,6′,2″′,2‴′,2‴‴′,2‴‴‴′,2‴‴‴‴′,2‴‴‴‴‴′-Tetradeca-O-methyl-β-cyclodextrin.

White or almost white powder.

Dimethyldecylamine. C_{12}H_{27}N. (M, 185.4). 1113500. [1120-24-7]. N,N-Dimethyldecylamine.

Content: minimum 98.0 per cent m/m of C_{12}H_{27}N.

bp: about 234 °C.

1,1-Dimethylethylamine. C_{4}H_{12}N. (M, 73.1). 1100900. [75-64-9]. 2-Amino-2-methylpropane. tert-Butylamine.

Liquid, miscible with alcohol.

d_{20}^{20}: 1.065.
n_{D}^{20}: 1.368.

bp: about 90 °C.

Dimethyl-β-cyclodextrin. C_{6}H_{14}O_{6}. (M, 1331). 1169100. [5116-71-3]. Heptakis(2,6-di-O-methyl)cyclomaltoheptaose. Cycloheptakis(1,4,2,6-di-O-methyl-α-D-glucopyranosyl). 2,2′,6′,2″′,2‴′,2‴‴′,2‴‴‴′,2‴‴‴‴′,2‴‴‴‴‴′-Tetradeca-O-methyl-β-cyclodextrin.

White or almost white powder.

Dimethyldecylamine. C_{12}H_{27}N. (M, 185.4). 1113500. [1120-24-7]. N,N-Dimethyldecylamine.

Content: minimum 98.0 per cent m/m of C_{12}H_{27}N.

bp: about 234 °C.

1,1-Dimethylethylamine. C_{4}H_{12}N. (M, 73.1). 1100900. [75-64-9]. 2-Amino-2-methylpropane. tert-Butylamine.

Liquid, miscible with alcohol.

d_{20}^{20}: 0.694.
n_{D}^{20}: 1.378.

bp: at 46 °C.

1,1-Dimethylethyl methyl ether. C_{4}H_{12}O. (M, 88.1). 1013900. [1634-04-4]. 2-Methoxy-2-methylpropane. tert-Butyl methyl ether.

A colourless, clear, flammable liquid.

Minimum transmittance (2.2.25), determined using water R as compensation liquid: 50 per cent at 240 nm, 80 per cent at 255 nm, 98 per cent at 280 nm.

1,1-Dimethylethyl methyl ether R1. 1126400.

Content: minimum 99.5 per cent of C_{4}H_{12}O.

d_{20}^{20}: 0.741.
n_{D}^{20}: 1.369.

bp: at 55 °C.

Dimethylformamide. C_{4}H_{8}N_{2}. (M, 73.1). 1030300. [68-12-2].

A clear, colourless neutral liquid, miscible with water and with alcohol.

d_{20}^{20}: 0.949 to 0.952.

bp: about 153 °C. Water (2.5.12): maximum 0.1 per cent.

Dimethylformamide diethylacetal. C_{6}H_{14}N_{2}O. (M, 147.2). 1113600. [1188-33-6]. N,N-Dimethylformamide diethylacetal.

bp: 128 °C to 130 °C.

N,N-Dimethylformamide dimethylacetal. C_{6}H_{14}NO_{2}. (M, 193.2). 1164000. [17469-89-5]. (2S)-2-(Dimethylamino)-3-phenylpropanoic acid.

mp: about 226 °C.

Dimethylpiperazine. C_{9}H_{15}N_{2}. (M, 142.2). 1008100. [95-65-8].

White or almost white crystals.

2,5-Dimethylphenol. C_{8}H_{10}O. (M, 122.2). 1162300. [95-87-4]. 3,4-Dimethylphenol.

mp: about 226 °C.

2,6-Dimethylphenol. C_{8}H_{10}O. (M, 122.2). 1030600. [1200900].

Colourless needles, slightly soluble in water, very soluble in alcohol.

bp: about 203 °C.

mp: 46 °C to 48 °C.

3,4-Dimethylphenol. C_{8}H_{10}O. (M, 122.2). 1098100. [95-65-8].

White or almost white crystals.

mp: about 226 °C.

Dimethylstearamide. C_{20}H_{41}NO. (M, 311.6). 1030800. N,N-Dimethylstearamide.

A white or almost white solid mass, soluble in many organic solvents, including acetone.

mp: about 51 °C.

Dimethylstearylamide. 1030800.

See dimethylstearamide R.

Dimethyl sulphone. C_{6}H_{10}S. (M, 94.1). 1030900. [67-74-0].

A white or almost white, crystalline powder, freely soluble in water, soluble in acetone and alcohol.

mp: 108 °C to 110 °C.
**Dimethyl sulfoxide.** 1029500. [67-68-5].
See Dimethyl sulfoxide (0763).
Dimethyl sulfoxide used in spectrophotometry complies with the following additional test.
*Minimum transmittance (2.2.25), determined using water R as compensation liquid: 10 per cent at 262 nm, 35 per cent at 270 nm, 70 per cent at 290 nm, 98 per cent at 340 nm and at higher wavelengths.*

**Dimethyl sulfoxide R1.** 1029501.
*Content: minimum 99.7 per cent of C4H8OS, determined by gas chromatography.*

**Dimeticone.** 1105400. [9016-00-6].
See Dimeticone (0138).

**Dimidium bromide.** C6H4BrN3. (M 380.3). 1031100.[518-67-2]. 3,8-Diamino-5-methyl-6-phenylphenanthridinium bromide.
Dark-red crystals, slightly soluble in water at 20 °C, sparingly soluble in water at 60 °C and in alcohol.

**Dimidium bromide-sulphane blue mixed solution.**
1031101.
Dissolve separately 0.5 g of dimidium bromide R and 0.25 g of sulphane blue R in 30 ml of a hot mixture of 1 volume of ethanol R and 9 volumes of water R, stir, the two solutions, and dilute to 250 ml with the same mixture of solvents. Mix 20 ml of this solution with 20 ml of a 14.0 per cent V/V solution of sulphuric acid R previously diluted with about 250 ml of water R and dilute to 500 ml with water R.
*Storage: protected from light.*

**Dinitrobenzene.** C6H4N2O4. (M 168.1). 1031200. [528-29-0]. 1,3-Dinitrobenzene.
Yellowish crystalline powder or crystals, practically insoluble in water, slightly soluble in alcohol.
mp: about 90 °C.

**Dinitrobenzene solution.** 1031201.
A 10 g/1 solution in alcohol R.

**Dinitrobenzoic acid.** C6H4N2O4. (M 212.1). 1031300.[99-34-3]. 3,5-Dinitrobenzoic acid.
Almost colourless crystals, slightly soluble in water, very soluble in alcohol.
mp: about 206 °C.

**Dinitrobenzoic acid solution.** 1031301.
A 20 g/1 solution in alcohol R.

Translucent, yellow or greenish-yellow powder or yellowish crystals, soluble in acetone and in toluene.
mp: about 68 °C.

**Suitability test.** To 1 ml of ethanol R and 0.1 g of dinitrobenzoyl chloride R add 0.05 ml of dilute sulphuric acid R and boil under a reflux condenser for 30 min. After evaporation on a water-bath add 5 ml of heptane R to the residue and heat to boiling. Filter the hot solution. Wash the crystals formed on cooling to room temperature with a small quantity of heptane R and dry in a desiccator. The crystals melt (2.2.14) at 94 °C to 95 °C.

**Dinitrophenylhydrazine.** C8H4N2O4. (M 198.1). 1031500.[119-26-6]. 2,4-Dinitrophenylhydrazine.
Reddish-orange crystals, very slightly soluble in water, slightly soluble in alcohol.
mp: about 203 °C (instantaneous method).

**Dinitrophenylhydrazine-aceto-hydrochloric solution.** 1031501.
Dissolve 0.2 g of dinitrophenylhydrazine R in 20 ml of methanol R and add 80 ml of a mixture of equal volumes of acetic acid R and hydrochloric acid R1. Prepare immediately before use.

**Dinitrophenylhydrazine-hydrochloric solution.** 1031502.
Dissolve by heating 0.5 g of dinitrophenylhydrazine R in dilute hydrochloric acid R and complete to 100 ml with the same solvent. Allow to cool and filter. Prepare immediately before use.

**Dinitrophenylhydrazine-sulphuric acid solution.** 1031503.
Dissolve 1.5 g of dinitrophenylhydrazine R in 50 ml of a 20 per cent V/V solution of sulphuric acid R. Prepare immediately before use.

**Dinonyl phthalate.** C26H42O4. (M 418.6). 1031600.[28553-12-0].
A colourless to pale yellow, viscous liquid.
*Acidity. Shake 5.0 g with 25 ml of water R for 1 min. Allow to stand, filter the separated aqueous layer and add 0.1 ml of phenolphthalein solution R. Not more than 0.3 ml of 0.1 M sodium hydroxide is required to change the colour of the solution (0.05 per cent, calculated as phthalic acid).*
*Water (2.5.12): maximum 0.1 per cent.*

**Dioctadecyl disulphide.** C56H112S2. (M 771.1). 1031700.[2500-88-1].
A white or almost white powder, practically insoluble in water.
mp: 53 °C to 58 °C.

**2,2′-Di(octadecyloxy)-5,5′-spiribitol(1,3,2-dioxaphosphorinane).** C56H112P2. (M 733). 1031800.
White or almost white, waxy solid, practically insoluble in water, soluble in hydrocarbons.
mp: 40 °C to 70 °C.

**Dioctadecyl 3,3′-thiodipropionate.** C56H112O4S. (M 683). 1031900.[693-36-7].
A white or almost white, crystalline powder, practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in acetone, in alcohol and in light petroleum.
mp: 58 °C to 67 °C.

**Dioxan.** C4H6O2. (M 88.1). 1032000.[123-91-1]. 1,4-Dioxan.
A clear, colourless liquid, miscible with water and with most organic solvents.
d20°: about 1.03.
*Freezing-point (2.2.18): 9 °C to 11 °C.*
*Water (2.5.12): maximum 0.5 per cent.*
*Do not distil if the dioxan does not comply with the test for peroxides.*
Peroxides. Place 8 ml of potassium iodide and starch solution R in a 12 ml ground-glass-stoppered cylinder about 1.5 cm in diameter. Fill completely with the substance to be examined, shake vigorously and allow to stand in the dark for 30 min. No colour is produced.

Dioxan used for liquid scintillation is of a suitable analytical grade.

**Dioxan solution.** 1032002.

Dilute 50.0 ml of dioxan stock solution R to 100.0 ml with water R. (0.5 mg/ml of dioxan).

**Dioxan solution R.** 1032003.

Dilute 10.0 ml of dioxan solution R to 50.0 ml with water R. (0.1 mg/ml of dioxan).

**Dioxan stock solution.** 1032001.

Dissolve 1.00 g of dioxan R in water R and dilute to 100.0 ml with the same solvent. Dilute 5.0 ml of this solution to 50.0 ml with water R (1.0 mg/ml).

**Diphenylamine.** C₆H₅N. (M, 169.2). 1032100. [122-39-4].

White or almost white crystals, slightly soluble in water, soluble in alcohol.

mp: about 55 °C.

**Storage:** protected from light.

**Diphenylamine solution.** 1032101.

A 1 g/l solution in sulphuric acid R.

**Storage:** protected from light.

**Diphenylamine solution R.** 1032102.

A 10 g/l solution in sulphuric acid R. The solution is colourless.

**Diphenylamine solution R.** 1032103.

Dissolve 1 g of diphenylamine R in 100 ml of glacial acetic acid R and add 2.75 ml of sulphuric acid R. Use immediately.

**Diphenylanthracene.** C₂₆H₁₈. (M, 336.4). 1032200. [1499-10-1]. 9,10-Diphenylanthracene.

mp: about 248 °C.

**Storage:** protected from light.

**Diphenylboric acid aminoethyl ester.** C₆H₅BNO. (M, 225.1). 1032400. [524-95-8].

A white or slightly yellow, crystalline powder, practically insoluble in water, soluble in alcohol.

mp: about 193 °C.


A white or almost white, crystalline powder which gradually becomes pink on exposure to air, very slightly soluble in water, soluble in acetonitrile, in alcohol and in glacial acetic acid.

mp: about 170 °C.

**Sulphated ash (2.4.14):** maximum 0.1 per cent.

**Storage:** protected from light.

**Diphenylcarbazide solution.** 1032501.

Dissolve 0.2 g of diphenylcarbazide R in 10 ml of glacial acetic acid R and dilute to 100 ml with ethanol R. Prepare immediately before use.

**Diphenylcarbazone.** C₁₃H₁₄N₂O. (M, 240.3). 1032600. [538-62-5]. 1,5-Diphenylcarbazone.

An orange-yellow, crystalline powder, practically insoluble in water, freely soluble in alcohol.

mp: about 157 °C, with decomposition.

**Diphenylcarbazone mercuric reagent.** 1032601.

**Solution I.** Dissolve 0.1 g of diphenylcarbazone R in ethanol R and dilute to 50 ml with the same solvent.

**Solution II.** Dissolve 1 g of mercuric chloride R in ethanol R and dilute to 50 ml with the same solvent.

Mix equal volumes of the two solutions.

1,2-Diphenylhydrazine. C₁₂H₁₄N₂. (M, 184.3). 1140800. [122-66-7]. Hydrazobenzene. 1,2-Diphenyldiazene.

Orange powder.

mp: about 125 °C.

**Diphenylmethanol.** C₁₂H₁₂O. (M, 184.2). 1145700. [91-01-0]. Benzhydrol.

A white or almost white, crystalline powder.

mp: about 66 °C.

**Diphenyloxazole.** C₁₃H₁₄NO. (M, 221.3). 1032700. [92-71-7]. 2,5-Diphenyloxazole.

A white or almost white powder, practically insoluble in water, soluble in methanol, sparingly soluble in dioxan and in glacial acetic acid.

mp: about 70 °C.

A1 cm⁻¹. about 1260 determined at 305 nm in methanol R.

**Diphenyloxazole used for liquid scintillation is of a suitable analytical grade.**

**Diphenylphenylene oxide polymer.** 1032800.

2,6-Diphenyl-1,4-phenylene oxide polymer.

White or almost white, porous beads. The size range of the beads is specified after the name of the reagent in the tests where it is used.

**Diphenylphenylene oxide polymer used for liquid scintillation is of a suitable analytical grade.**

**Diphosphorus pentoxide.** P₂O₅. (M, 141.9). 1032900. [1314-56-3]. Phosphorus pentoxide. Phosphoric anhydride.

A white or almost white powder, amorphous, deliquescent. It is hydrated by water with the evolution of heat.

**Storage:** in an airtight container.

**Dipotassium hydrogen phosphate.** K₂HPO₄. (M, 174.2). 1033000. [7758-11-4].

A white or almost white, crystalline powder, hygroscopic, very soluble in water, slightly soluble in alcohol.

**Storage:** in an airtight container.

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**General Notices (1) apply to all monographs and other texts**
4.1.1. Reagents

Disodium arsenate. \( \text{Na}_2\text{HAsO}_4\cdot7\text{H}_2\text{O} \). (\( M \), 228.2). 1157600. [1678-85-7].
Colourless or white or almost white powder or crystals, freely soluble in water.

Disodium sulphate. \( \text{K}_2\text{SO}_4 \). (\( M \), 174.3). 1033100. [7778-80-5].
Colourless crystals, soluble in water.

2,2′-Dipyridyldiamine. \( \text{C}_2\text{H}_6\text{N}_2 \). (\( M \), 171.2). 1157700. [1202-34-2]. \( N \)\((\text{Pyridin-2-yl})\text{pyridin-2-amine.} \)
mp: about 95 °C.

Disodium arsenate. \( \text{Na}_2\text{HAsO}_4\cdot7\text{H}_2\text{O} \). (\( M \), 312.0). 1102500. [10048-95-0]. Disodium hydrogen arsenate heptahydrate. Dibasic sodium arsenate.
Crystals, efflorescent in warm air, freely soluble in water, soluble in glycerol, slightly soluble in alcohol. The aqueous solution is alcaline to litmus.

Disodium hydrogen phosphate dihydrate. \( \text{Na}_2\text{HPO}_4\cdot7\text{H}_2\text{O} \). (\( M \), 388.3). 1126600. [979-88-4]. Sodium acid phosphate.
mp: about 30 °C.

Disodium hydrogen phosphate. \( \text{Na}_2\text{HPO}_4 \). (\( M \), 144-33-2). Sodium acid phosphate.
Storage: in an airtight container.

Disodium tetraborate. \( \text{Na}_2\text{B}_4\text{O}_7\cdot10\text{H}_2\text{O} \). (\( M \), 428). 1102500. [1097300]. Sodium tetraborate.
Storage: in an air-tight container.

Disodium hydrogen phosphate. \( \text{Na}_2\text{HPO}_4 \). (\( M \), 1102500. [1097300]. Sodium tetraborate.
Storage: in an air-tight container.

Dithiol. \( \text{C}_8\text{H}_8\text{S}_2 \). (\( M \), 156.3). 1033800. [496-74-2]. Toluene-3,4-dithiol. 4-Methylbenzene-2,3-dithiol.
White or almost white crystals, hygroscopic, soluble in methanol and in solutions of alkali hydroxides.
mp: about 30 °C.
Storage: in an airtight container.

Dithiothreitol. \( \text{C}_7\text{H}_8\text{S}_2 \). (\( M \), 154.2). 1098200. [27565-41-9]. three-1,4-Dimercaptobutane-2,3-diol.
Slightly hygroscopic needles, freely soluble in water, in acetone and in ethanol.
Storage: in an airtight container.

Dithizone. \( \text{C}_3\text{H}_9\text{N}_2\text{S} \). (\( M \), 256.3). 1033900. [60-10-6]. 1,5-Diphenylthiocarbazone.
A bluish-black, brownish-black or black powder, practically insoluble in water, soluble in alcohol.
Storage: protected from light.

Dithiozone solution. 1033901.
A 0.5 g/l solution in chloroform R. Prepare immediately before use.

Dithizone solution R2. 1033903.
Dissolve 40.0 mg of dithizone R in chloroform R and dilute to 1000.0 ml with the same solvent. Dilute 30.0 ml of the solution to 100.0 ml with chloroform R.

Standardisation. Dissolve a quantity of mercuric chloride R equivalent to 0.1354 g of HgCl₂ in a mixture of equal volumes of dilute sulphuric acid R and water R and dilute to 100.0 ml with the same mixture of solvents.
Dilute 2.0 ml of this solution to 100.0 ml with a mixture of equal volumes of dilute sulphuric acid R and water R. (This solution contains 20 ppm of Hg). Transfer 1.0 ml of the solution to a separating funnel and add 50 ml of dilute sulphuric acid R, 140 ml of water R and 10 ml of a 200 g/l solution of hydroxyamine hydrochloride R.
Titrate with the dithizone solution; after each addition, shake the mixture twenty times and towards the end of the titration allow to separate and discard the chloroform layer. Titrate until a bluish-green colour is obtained.
Calculate the equivalent in micrograms of mercury per millilitre of the dithizone solution from the expression 20/\( V\), where \( V\) is the volume in millilitres of the dithizone solution used in the titration.

Dithizone solution R1. \( \text{C}_3\text{H}_9\text{N}_2\text{S} \). (\( M \), 256.3). 1105500. [60-10-6]. 1,5-Diphenylthiocarbazone.
Content: minimum 98.0 per cent of \( \text{C}_3\text{H}_9\text{N}_2\text{S} \).
A bluish-black, brownish-black or black powder, practically insoluble in water, soluble in alcohol.
Storage: protected from light.

Divanadium pentoxide. \( \text{V}_2\text{O}_5 \). (\( M \), 181.9). 1034000. [1314-62-1]. Vanadic anhydride.
Content: minimum 98.5 per cent of \( \text{V}_2\text{O}_5 \).
A yellow-brown to rust-brown powder, slightly soluble in water, soluble in strong mineral acids and in solutions of alkali hydroxides with formation of salts.
Appearance of solution. Heat 1 g for 30 min with 10 ml of sulphuric acid R. Allow to cool and dilute to 10 ml with the same acid. The solution is clear (2.2.1).
Sensitivity to hydrogen peroxide. Dilute 1.0 ml of the solution prepared for the test for appearance of solution cautiously to 50.0 ml with water R. To 0.5 ml of the solution add 0.1 ml of a solution of hydrogen peroxide R (0.1 g/1 of H₂O₂). The solution has a distinct orange colour compared with a blank prepared from 0.5 ml of the solution to be examined and 0.1 ml of water R. After the addition of 0.4 ml of hydrogen peroxide solution (0.1 g/1 H₂O₂), the orange solution becomes orange-yellow.

Loss on ignition: maximum 1.0 per cent, determined on 1.00 g at 700 ± 50 °C.

Assay. Dissolve 0.200 g with heating in 20 ml of a 70 per cent m/m solution of sulphuric acid R. Add 100 ml of water R and 0.02 M potassium permanganate until a reddish colour is obtained. Decolorise the excess of potassium permanganate by the addition of a 30 g/l solution of sodium nitrite R. Add 5 g of urea R and 80 ml of a 70 per cent m/m solution of sulphuric acid R. Cool. Using 0.1 ml of ferroin R as indicator, titrate the solution immediately with 0.1 M ferrous sulphate until a greenish-red colour is obtained. 1 ml of 0.1 M ferrous sulphate is equivalent to 9.095 mg of V₂O₅.

Divanadium pentoxide solution in sulphuric acid. 1034001.

Dissolve 0.2 g of divanadium pentoxide R in 4 ml of sulphuric acid R and dilute to 100 ml with water R.


Content: minimum 90.0 per cent of C₃₀H₄₆O₂, determined by gas chromatography.

Docusate sodium. 1034100. [577-11-7].

See Docusate sodium (1418).

Dodecyltrimethylammonium bromide. C₁₅H₃₄BrN. See H₂O₂). The solution has a distinct orange colour compared with a blank prepared from 0.5 ml of the solution to be examined and 0.1 ml of water R. After the addition of 0.4 ml of hydrogen peroxide solution (0.1 g/1 H₂O₂), the orange solution becomes orange-yellow.

Electrolyte reagent for the micro determination of water. 1113700.

Commercially available anhydrous reagent or a combination of anhydrous reagents for the coulometric titration of water, containing suitable organic bases, sulphur dioxide and iodide dissolved in a suitable solvent.

Elementary standard solution for atomic spectrometry (1.000 g/l). 5004000.

This solution is prepared, generally in acid conditions, from the element or a salt of the element whose minimum content is not less than 99.0 per cent. The quantity per litre of solution is greater than 0.995 g throughout the guaranteed period, as long as the vial has not been opened. The starting material (element or salt) and the characteristics of the final solvent (nature and acidity, etc.) are mentioned on the label.

Emetine dihydrochloride. 1034300. [316-42-7]. See Emetine hydrochloride pentahydrate (0081).

Emodin. C₁₅H₁₀O₇. 1034400. [518-82-1]. 1,3,8-Trimethoxy-6-methylanthraquinone. Orange-red needles, practically insoluble in water, soluble in alcohol and in solutions of alkali hydroxides.

Chromatography. Examine as prescribed in the monograph on Rhubarb (0291); the chromatogram shows only one principal spot.


bp: about 200 °C.

mp: about 108 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.


bp: about 390 °C.

mp: about 207 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Endrin. C₁₀H₈Cl₆O. (M, 380.9). 1127000. [72-20-8].

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Eucamidine. C₁₀H₁₃NO. (M, 337.6). 1034500. [112-84-5].

(Z)-Docos-13-enoamide. Yellowish or white powder or granules, practically insoluble in water, very soluble in methylene chloride, soluble in ethanol.

mp: about 70 °C.

Erythritol. 113800. [149-32-6].

See Erythritol (1803).
4.1.1. Reagents

See the information section on general monographs (cover pages)

**Escurin.** C₉H₆O₉·½H₂O. *(M, 367.3).* 1119400. [531-75-9].

A white to almost white powder or colourless crystals, sparingly soluble in water and in alcohol, freely soluble in hot water and in hot alcohol.

**Chromatography** (2.2.27). Examine as prescribed in the monograph on *Eleutherococcus* (1419). The chromatogram shows only one principal spot.

**Estradiol.** C₁₈H₂₄O₂. *(M, 272.4).* 1135600. [50-28-2].

Prisms stable in air, practically insoluble in water, freely soluble in alcohol, soluble in acetone and in dioxane, sparingly soluble in vegetable oils.

**Estragole.** C₁₅H₁₀O₂. *(M, 272.4).* 1034600. [57-91-0].

A white or almost white, crystalline powder or colourless crystals.

**Ethanol.** *Anhydrous.* *(M, 46.06).* 1034800. [64-17-5].

See *Ethanol, anhydrous R.*

**Ethanol, anhydrous.** 1034800. [64-17-5].

See *Ethanol, anhydrous R.*

**Ether.** *(M, 74.1).* 1035000. [60-29-7].

A clear, colourless, viscous, hygroscopic liquid, miscible with water and with methanol.

**Ethanolamine.** C₇H₁₄NO. *(M, 111.17).* 1034900. [141-43-5].

2-Aminoethanol.

Inject 1 µl of the test solution and 1 µl of the reference solution, alternately, three times. After each chromatography, heat the column to 230 °C for 8 min. Integrate the methanol peak. Calculate the percentage methanol content from the expression:

\[
\frac{a \times b}{c - b}
\]

**Estragole used in gas chromatography** complies with the following test.

**Assay.** Examine by gas chromatography (2.2.28) under the conditions described in the monograph on *Anise oil* (0804) using the substance to be examined as the test solution.

The area of the principal peak is not less than 98.0 per cent of the total area of the peaks.

**Ethanol.** 1034800. [64-17-5].

See *Ethanol, anhydrous R.*

**Ethanol, anhydrous.** 1034800. [64-17-5].

See *Ethanol, anhydrous R.*

**Ethanol R1.** 1034801.

Complies with the requirements prescribed for the monograph *Ethanol, anhydrous R* and with the following requirement.

**Methanol:** maximum 0.005 per cent V/V, determined by gas chromatography (2.2.28).

**Test solution.** Use the substance to be examined.

**Reference solution.** Dilute 0.50 ml of anhydrous methanol R to 100.0 ml with the substance to be examined. Dilute 1.0 ml of this solution to 100.0 ml with the substance to be examined.

The chromatographic procedure may be carried out using:

- a glass column 2 m long and 2 mm in internal diameter packed with ethylvinylenbenzene-divinyl-benzene copolymer R (75 µm to 100 µm),
- nitrogen for chromatography R as the carrier gas at a flow rate of 30 ml/min,
- a flame-ionisation detector.

Maintain the temperature of the column at 130 °C, that of the injection port at 150 °C and that of the detector at 200 °C.

Inject 1 µl of the test solution and 1 µl of the reference solution, alternately, three times. After each chromatography, heat the column to 230 °C for 8 min. Integrate the methanol peak. Calculate the percentage methanol content from the expression:

\[
\frac{a \times b}{c - b}
\]

**Estragole used in gas chromatography** complies with the following test.

**Assay.** Examine by gas chromatography (2.2.28) under the conditions described in the monograph on *Anise oil* (0804)

Inject 1 µl of the test solution and 1 µl of the reference solution, alternately, three times. After each chromatography, heat the column to 230 °C for 8 min. Integrate the methanol peak. Calculate the percentage methanol content from the expression:

\[
\frac{a \times b}{c - b}
\]

**Estragole used in gas chromatography** complies with the following test.

**Assay.** Examine by gas chromatography (2.2.28) under the conditions described in the monograph on *Anise oil* (0804) using the substance to be examined as the test solution.

The area of the principal peak is not less than 98.0 per cent of the total area of the peaks.

**Ethanol.** 1002500. [64-17-5].

See *Ethanol (96 per cent).*

**Ethanol (x per cent V/V).** 1002502.

Mix appropriate volumes of *water R* and *ethanol (96 per cent) R* allowing for the effects of warming and volume contraction inherent to the preparation of such a mixture, to obtain a solution whose final content of ethanol corresponds to the value of x.

**Ethanolamine.** C₇H₁₄NO. *(M, 111.17).* 1034900. [141-43-5].

2-Aminoethanol.

A clear, colourless, viscous, hygroscopic liquid, miscible with water and with methanol.

**Ether.** *(M, 74.1).* 1035000. [60-29-7].

A clear, colourless, volatile and very mobile liquid, very flammable, hygroscopic, soluble in water, miscible with alcohol.

**Ether, peroxide-free.** 1035100.

Do not distil if the ether does not comply with the test for peroxides.

**Peroxides.** Place 8 ml of potassium iodide and starch solution R in a 12 ml ground-glass-stoppered cylinder about 1.5 cm in diameter. Fill completely with the substance to be examined, shake vigorously and allow to stand in the dark for 30 min. No colour is produced.

The name and concentration of any added stabilisers are stated on the label.

**Ether:** an airtight container.

**Ether.** *(M, 74.1).* 1035000. [60-29-7].

A clear, colourless, volatile and very mobile liquid, very flammable, hygroscopic, soluble in water, miscible with alcohol.

**Ether, peroxide-free.** 1035100.

See *Anaesthetic ether (0367).*

**Ethyon.** C₉H₂₂O₄P₂S₄. *(M, 384.5).* 1127100. [563-12-2].

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

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Ethoxycrysoidine hydrochloride. C$_{14}$H$_{17}$ClN$_{4}$O. (M, 292.8). 1035290. [2313-87-3]. 4-(4-Ethoxyphenyl)diazeryl[phenyl-1,3-diamine hydrochloride.
A reddish powder, soluble in alcohol.

Ethoxycrysoidine solution. 1035201.
A 1 g/1 solution in alcohol R.

Test for sensitivity. To a mixture of 5 ml of dilute hydrochloric acid R and 0.05 ml of the ethoxy-chrysoidine solution add 0.05 ml of 0.0167 M bromide-bromate. The colour changes from red to light yellow within 2 min.

Ethyl acetate. C$_{4}$H$_{8}$O$_{2}$. (Ethyl prop-2-enoate.
bp: about 135 °C.

Ethyl benzoate. C$_{9}$H$_{10}$O$_{2}$. (bp: about 116 °C.

Ethylene acrylate. C$_{5}$H$_{8}$O$_{2}$. (bp: about 135 °C.

Ethylene bis[3,3-di(1,1-dimethylethyl)-4-hydroxyphenyl]butyrate]. C$_{50}$H$_{66}$O$_{8}$. [32509-66-3].

Ethylene glycol. C$_{2}$H$_{6}$O$_{2}$. (Ethylene glycol monoethyl ether. C$_{2}$H$_{5}$O$_{2}$. (bp: about 76 °C to 78 °C.

Ethylene glycol monoethyl ether. C$_{2}$H$_{5}$O$_{2}$. (bp: about 205 °C to 209 °C, with decomposition.

Ethylene chlorohydrin. C$_{2}$H$_{4}$Cl. (Ethylene chloride.
bp: 211 °C to 213 °C.

Ethylene bis[3,3-di(3-tert-butyl-4-hydroxyphenyl)butyrate]. 1035900. [32509-66-3].
See ethylene bis[3,3-di(3-(1,1-dimethylethyl)-4-hydroxyphenyl)butyrate] R.

Ethylene glycol monoethyl ether. C$_{2}$H$_{5}$O$_{2}$. (M, 90.1). 1036200. [110-80-5]. 2-Ethoxyethanol.

Content: minimum 99.0 per cent.

A clear, colourless liquid, miscible with water, with ethanol (96 per cent).
d$_{20}$: 0.901 to 0.904.
bp: 104 °C to 109 °C.

Ethylene glycol monoethyl ether. C$_{2}$H$_{5}$O$_{2}$. (M, 90.1). 1036200. [110-80-5]. 2-Ethoxyethanol.

Content: minimum 99.0 per cent.

A clear, colourless liquid, miscible with water, with ethanol (96 per cent).
d$_{20}$: 0.901 to 0.904.
bp: 104 °C to 109 °C.

Ethylene glycol monoethyl ether. C$_{2}$H$_{5}$O$_{2}$. (M, 90.1). 1036200. [110-80-5]. 2-Ethoxyethanol.

Content: minimum 99.0 per cent.

A clear, colourless liquid, miscible with water, with ethanol (96 per cent).
de: 0.98.
mp: about 99 °C.

Ethylene glycol. C$_{2}$H$_{6}$O$_{2}$. (bp: about 99 °C.

Ethyl acetate. C$_{4}$H$_{8}$O$_{2}$. (Ethyl prop-2-enoate.
bp: about 135 °C.

Ethyl benzoate. C$_{9}$H$_{10}$O$_{2}$. (bp: about 98 °C.

Ethane-1,2-diamine. C$_{2}$H$_{8}$N$_{2}$. (M, 106.2). 1035800. [33403-97-3].

A pale yellow liquid.
d$_{20}^{20}$: about 0.984.
mp: about –71 °C.

Ethylene oxide. C$_{2}$H$_{4}$O. (M, 44.06). 1007500. [107-06-2].

A colourless liquid, miscible with water, with acetone and with light petroleum.
d$_{20}^{20}$: about 1.516.
bp: about 98 °C.

Ethylene glycol. C$_{2}$H$_{6}$O$_{2}$. (M, 62.1). 1036100. [107-21-1]. Ethene-1,2-diol.

Content: minimum 99.0 per cent.

A colourless, slightly viscous liquid, hygroscopic, miscible with water and with ethanol.
d$_{20}^{20}$: 1.113 to 1.115.
mp: about 250 °C, with decomposition.

Ethylene chlorohydrin. C$_{2}$H$_{4}$Cl. (Ethylene chloride.
bp: 211 °C to 213 °C.

Ethylene glycol. C$_{2}$H$_{6}$O$_{2}$. (M, 90.1). 1036200. [110-80-5]. 2-Ethoxyethanol.

Content: minimum 99.0 per cent.

A clear, colourless liquid, miscible with water, with acetone and with ethanol (96 per cent).
d$_{20}^{20}$: about 0.93.
mp: about 135 °C.
4.1.1. Reagents


Content: minimum 99.0 per cent.
A clear, colourless liquid, miscible with water, with acetone and with ethanol (96 per cent).

Density: about 0.97.


bp: about 125 °C.

Liquefaction point: about 12 °C.

Ethylene oxide solution. 1036402.
Weigh a quantity of ethylene oxide stock solution R equivalent to 2.5 mg of ethylene oxide into a cool flask and dilute to 50.0 ml with macrogol 200 R1. Mix well and dilute 2.5 g of this solution to 25.0 ml with macrogol 200 R1 (5 µg of ethylene oxide per gram of solution). Prepare immediately before use.

Ethylene oxide solution R1. 1036403.
Dilute 1.0 ml of cooled ethylene oxide stock solution R (check the exact volume by weighing) to 50.0 ml with macrogol 200 R1. Mix well and dilute 2.5 g of this solution to 25.0 ml with macrogol 200 R1. Calculate the exact amount of ethylene oxide in ppm from the volume determined by weighing and taking the relative density of macrogol 200 R1 as 1.127. Prepare immediately before use.

Ethylene oxide solution R2. 1036404.
Weigh 1.00 g of cold ethylene oxide stock solution R (equivalent to 2.5 mg of ethylene oxide) into a cool flask containing 40.0 g of cold macrogol 200 R1. Mix and determine the exact mass and dilute to a calculated mass to obtain a solution containing 50 µg of ethylene oxide per gram of solution. Weigh 10.00 g into a flask containing about 30 ml of water R, mix and dilute to 50.0 ml with water R (10 µg/ml of ethylene oxide). Prepare immediately before use.

Ethylene oxide solution R3. 1036405.
Dilute 10.0 ml of ethylene oxide solution R2 to 50.0 ml with water R (2 µg/ml of ethylene oxide). Prepare immediately before use.

Ethylene oxide solution R4. 1036407.
Dilute 1.0 ml of ethylene oxide stock solution R1 to 100.0 ml with water R. Dilute 1.0 ml of this solution to 25.0 ml with water R.

Ethylene oxide solution R5. 1036408.
A 50 g/l solution of ethylene oxide R in methylene chloride R.

Either use a commercially available reagent or prepare the solution corresponding to the above-mentioned composition.

Ethylene oxide stock solution. 1036401.
All operations carried out in the preparation of these solutions must be conducted in a fume-hood. The operator must protect both hands and face by wearing polyethylene protective gloves and an appropriate face mask.

Store all solutions in an airtight container in a refrigerator at 4 °C to 8 °C. Carry out all determinations three times.

Into a dry, clean test-tube, cooled in a mixture of 1 part of sodium chloride R and 3 parts of crushed ice, introduce a slow current of ethylene oxide R gas, allowing condensation onto the inner wall of the test-tube. Using a glass syringe, previously cooled to −10 °C, inject about 300 µl (corresponding to about 0.25 g) of liquid ethylene oxide R into 50 ml of macrogol 200 R1. Determine the absorbed quantity of ethylene oxide by weighing before and after absorption (Mₐ). Dilute to 100.0 ml with macrogol 200 R1. Mix well before use.

Assay. To 10 ml of a 500 g/l suspension of magnesium chloride R in ethanol R add 20.0 ml of 0.1 M alcoholic hydrochloric acid in a flask. Stopper and shake to obtain a saturated solution and allow to stand overnight to equilibrate. Weigh 5.00 g of ethylene oxide stock solution (2.5 g/l) R into the flask and allow to stand for 30 min.

Titrte with 0.1 M alcoholic potassium hydroxide determining the end-point potentiometrically (2.2.20).

Carry out a blank titration, replacing the substance to be examined with the same quantity of macrogol 200 R1. Ethylene oxide content in milligrams per gram is given by:

\[
V_b - V_e \times f \times 4.404 \div \frac{m}{\text{ml}}
\]

Where \(V_b\) and \(V_e\) are the volumes of alcoholic potassium hydroxide used respectively for the blank titration and the assay,

\[ f = \text{factor of the alcoholic potassium hydroxide solution,} \]

\[ m = \text{mass of the sample taken (g).} \]

Ethylene oxide stock solution R1. 1036406.
A 50 mg/ml solution of ethylene oxide R in methanol R.

A clear, colourless, flammable liquid, freely soluble in water, miscible with alcohol.

Density: about 0.919.

Ethyl formate solution. 1036409.
Weigh 1.00 g of ethyl formate stock solution R (equivalent to 2.5 mg of ethyl formate) into a cool flask containing 40.0 g of cold macrogol 200 R1. Mix and determine the exact mass and dilute to a calculated mass to obtain a solution containing 50 µg of ethyl formate per gram of solution. Weigh 10.00 g into a flask containing about 30 ml of water R, mix and dilute to 50.0 ml with water R (10 µg/ml of ethyl formate). Prepare immediately before use.

Ethyl formate solution R1. 1036410.
Dilute 1.0 ml of ethyl formate stock solution R to 50.0 ml with water R (2 µg/ml of ethyl formate). Prepare immediately before use.

Ethyl formate solution R2. 1036412.
Dilute 1.0 ml of ethyl formate stock solution R1 to 100.0 ml with water R. Dilute 1.0 ml of this solution to 25.0 ml with water R.

Ethyl formate solution R3. 1036414.
A 50 g/l solution of ethyl formate R in methylene chloride R.

Either use a commercially available reagent or prepare the solution corresponding to the above-mentioned composition.

Related substances. Examine by gas chromatography (2.2.28). Inject 1 µl of a solution prepared as follows: suspend 0.2 g of the 2-ethylhexanoic acid in 5 ml of water R, add 3 ml of dilute hydrochloric acid R and 5 ml of hexane R, shake for 1 min, allow the layers to separate and use the upper layer. Carry out the chromatographic procedure as prescribed in the test for 2-ethylhexanoic acid in the monograph on Amoxicillin sodium (0577). The sum of the
area of any peaks, apart from the principal peak and the peak due to the solvent, is not greater than 2.5 per cent of the area of the principal peak.

**Ethyl 4-hydroxybenzoate.** 1035700. [120-47-8]. See Ethyl parahydroxybenzoate R.

**2-Ethylmaleimide.** C₇H₈NO₂. (M, 125.1). 1036700. [128-53-0]. 1-Ethyl-1H-pyrrole-2,5-dione.

Colourless crystals, sparingly soluble in water, freely soluble in alcohol.

mp: 41 °C to 45 °C.

Storage: at a temperature of 2 °C to 8 °C.

**Ethyl methyl ketone.** 1054100. [78-93-3]. See methyl ethyl ketone R.


mp: 104 °C to 107 °C.

Storage: protected from moisture at 4 °C; use within 1 year.

**Ethyl parahydroxybenzoate.** 1035700. [120-47-8]. See Ethyl parahydroxybenzoate (9000).

2-Ethylpyridine. C₇H₉N. (1036900. [1133400. [100-71-0]. Colourless or brownish liquid.

Density (d₂₀): about 0.939.

nD: about 1.496.

bp: about 149 °C.

**Ethylvinylenzene-divinylbenzene copolymer.** 1036900.

Porous, rigid, cross-linked polymer beads. Several grades are available with different sizes of beads. The size range of the beads is specified after the name of the reagent in the tests where it is used.

**Ethylvinylenzene-divinylbenzene copolymer R1.** 1036901.

Porous, rigid, cross-linked polymer beads, with a nominal specific surface area of 500 m²/g to 600 m²/g and having pores with a mean diameter of 7.5 nm. Several grades are available with different sizes of beads. The size range of the beads is specified after the name of the reagent in the tests where it is used.

**Eugenol.** C₁₀H₁₄O₂. (M, 164.2). 1037000. [97-53-0]. 4-Allenyl-2-methoxyphenol.

A colourless or pale yellow, oily liquid, darkening on exposure to air and light and becoming more viscous, practically insoluble in water, miscible with alcohol and with fatty and essential oils.

Density (d₂₀): about 1.07.

bp: about 250 °C.

Eugenol used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Clove oil (1091) using the substance to be examined as the test solution.

The area of the principal peak is not less than 98.0 per cent of the total area of the peaks.

Storage: protected from light.

**Euglobulins, bovine.** 1037100.

Use fresh bovine blood collected into an anticoagulant solution (for example, sodium citrate solution). Discard any haemolysed blood. Centrifuge at 1500 g to 1800 g at 15 °C to 20 °C to obtain a supernatant plasma poor in platelets.

To 1 litre of bovine plasma add 75 g of barium sulphate R and shake for 30 min. Centrifuge at not less than 1500 g to 1800 g at 15 °C to 20 °C and draw off the clear supernatant liquid. Add 10 ml of a 0.2 mg/ml solution of aprotinin R and shake to ensure mixing. In a container with a minimum capacity of 30 litres in a chamber at 4 °C introduce 25 litres of distilled water R at 4 °C and add about 500 g of solid carbon dioxide. Immediately add, while stirring, the supernatant liquid obtained from the plasma. A white precipitate is formed. Allow to settle at 4 °C for 10 h to 15 h. Remove the clear supernatant solution by siphoning. Collect the precipitate by centrifuging at 4 °C. Suspend the precipitate by dispersing mechanically in 500 ml of distilled water R at 4 °C, shake for 5 min and collect the precipitate by centrifuging at 4 °C. Disperse the precipitate mechanically in 60 ml of a solution containing 9 g/l of sodium chloride R and 0.9 g/l sodium citrate R and adjust to pH 7.2 to 7.4 by adding a 10 g/l solution of sodium hydroxide R. Filter through a sintered glass filter (2.1.2); to facilitate the dissolution of the precipitate crush the particles of the precipitate with a suitable instrument. Wash the filter and the instrument with 40 ml of the chloroform-citrate solution described above and dilute to 100 ml with the same solution. Freeze-dry the solution. The yields are generally 6 g to 8 g of euglobulins per litre of bovine plasma.

Test for suitability. For this test, prepare the solutions using phosphate buffer solution pH 7.4 containing 30 g/l of bovine albumin R.

Into a test-tube 8 mm in diameter placed in a water-bath at 37 °C introduce 0.2 ml of a solution of a reference preparation of urokinase containing 100 IU/ml and 0.1 ml of a solution of human thrombin R containing 20 IU/ml.

Add rapidly 0.5 ml of a solution containing 10 mg of bovine euglobulins per millilitre. A firm clot forms in less than 10 s. Note the time that elapses between the addition of the solution of bovine euglobulins and the lysis of the clot. The lysis time does not exceed 15 min.

Storage: protected from moisture at 4 °C; use within 1 year.

**Euglobulins, human.** 1037200.

For the preparation, use fresh human blood collected into an anticoagulant solution (for example sodium citrate solution) or human blood for transfusion that has been collected in plastic blood bags and which has just reached its expiry date. Discard any haemolysed blood. Centrifuge at 1500 g to 1800 g at 15 °C to obtain a supernatant plasma poor in platelets. Iso-group plasma may be mixed.

To 1 litre of the plasma add 75 g of barium sulphate R and shake for 30 min. Centrifuge at not less than 15 000 g at 15 °C and draw off the clear supernatant liquid. Add 10 ml of a solution of aprotinin R containing 0.2 mg/ml and shake to ensure mixing. In a container with a minimum capacity of 30 litres in a chamber at 4 °C introduce 25 litres of distilled water R at 4 °C and add about 500 g of solid carbon dioxide. Immediately add while stirring the supernatant liquid obtained from the plasma. A white precipitate is formed. Allow to settle at 4 °C for 10 h to 15 h. Remove the clear supernatant solution by siphoning. Collect the precipitate by centrifuging at 4 °C. Suspend the precipitate by dispersing mechanically in 500 ml of distilled water R at 4 °C, shake for 5 min and collect the precipitate by centrifuging at 4 °C. Disperse the precipitate mechanically in 60 ml of a solution containing 9 g/l of sodium chloride R and 0.9 g/l sodium citrate R and adjust the pH to 7.2 to 7.4 by adding a 10 g/l solution of sodium hydroxide R. Filter through a sintered glass filter (2.1.2); to facilitate the dissolution of the precipitate crush the particles of the precipitate with a suitable instrument. Wash the filter and the instrument...
with 40 ml of the chloride-citrate solution described above and dilute to 100 ml with the same solution. Freeze-dry the solution. The yields are generally 6 g to 8 g of euglobulins per litre of human plasma.

Test for suitability. For this test, prepare the solutions using phosphate buffer solution pH 7.2 R containing 30 g/l of bovine albumin R. Into a test-tube 8 mm in diameter placed in a water-bath at 37 °C introduce 0.1 ml of a solution of a reference preparation of streptokinase containing 10 IU of streptokinase activity per millilitre and 0.1 ml of a solution of human thrombin R containing 20 IU/ml. Add rapidly 1 ml of a solution containing 10 mg of human euglobulins per millilitre. A firm clot forms in less than 10 s. Note the time that elapses between the addition of the solution of human euglobulins and the lysis of the clot. The lysis time does not exceed 15 min.

Storage: in an airtight container at 4 °C; use within 1 year.

Factor Xa, bovine, coagulation. 1037300. [0002-05-5]. An enzyme which converts prothrombin to thrombin. The semi-purified preparation is obtained from liquid bovine plasma and it may be prepared by activation of the zymogen factor X with a suitable activator such as Russell’s viper venom.

Store freeze-dried preparation at −20 °C and frozen solution at a temperature lower than −20 °C.

Factor Xa solution, bovine. 1037301. Reconstitute as directed by the manufacturer and dilute with tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R.

Any change in the absorbance of the solution, measured at 405 nm (2.2.25) against tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R and from which the blank absorbance has been subtracted, is not more than 0.20 per minute.

Factor Xa solution, bovine R1. 1037302. Reconstitute as directed by the manufacturer and dilute to 1.4 nkat/ml with tris(hydroxymethyl)aminomethane EDTA buffer solution pH 8.4 R.

(E,E)-Farnesol. C_{15}H_{26}O. (M: 222.4). 1161000. [106-28-5].

trans,trans-Farnesol. (2E,6E)-3,7,11-Trimethyldodeca-2,6,10-trien-1-ol.

Fast blue B salt. C_{17}H_{13}N_{2}O_{2} (M: 339.2). 1037400. [84633-94-3].

Schultz No. 490. A dark green powder, soluble in water. It is stabilised by addition of zinc chloride.

Storage: in an airtight container, at a temperature between 2 °C and 8 °C.

Fast red B salt. C_{17}H_{13}N_{2}O_{2}S_{2} (M: 467.4). 1037500. [56315-29-8].

Schultz No. 155.

Colour Index No. 37125.

2-Methoxy-4-nitrobenzenediazonium hydrogen naphthalene-1,5-disulphonate. An orange-yellow powder, soluble in water, slightly soluble in alcohol.

Storage: in an airtight container, protected from light, at 2 °C to 8 °C.

**Fenchlorphos.** C_{16}H_{15}ClO_{2}PS. (M, 321.5). 1127200. [299-84-3].

mp: about 35 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

**Fenchone.** C_{16}H_{24}O. (M, 152.2). 1037600. [7787-20-4].

(1R)-1,3,3-Trimethylbicyclo[2.2.1]heptan-2-one. Oily liquid, miscible with ethanol (96 per cent), practically insoluble in water.

n_{D}^{20}: about 1.46.

bp: 192 °C to 194 °C.

Fenchone used in gas chromatography complies with the following test.

Assay. Gas chromatography (2.2.28) as prescribed in the monograph on Bitter fennel (0824).

**Ferric ammonium sulphate.** FeNH_{3}(SO_{4})_{2}·12H_{2}O. (M, 482.2). 1037700. [7783-83-7]. Ammonium iron disulphate dodecahydrate.

Pale-violet crystals, efflorescent, very soluble in water, practically insoluble in alcohol.

**Ferric ammonium sulphate solution R2.** 1037702. A 100 g/l solution. If necessary filter before use.

**Ferric ammonium sulphate solution R5.** 1037704. Shake 30.0 g of ferric ammonium sulphate R with 40 ml of nitric acid R and dilute to 100 ml with water R. If the solution is turbid, centrifuge or filter it.

**Ferric ammonium sulphate solution R6.** 1037705. Dissolve 20 g of ferric ammonium sulphate R in 75 ml of water R, add 10 ml of a 2.8 per cent V/V solution of sulphuric acid R and dilute to 100 ml with water R.

**Ferric chloride.** FeCl_{3}·6H_{2}O. (M, 270.3). 1037800. [10025-77-1]. Iron trichloride hexahydrate.

Yellowish-orange or brownish crystalline masses, deliquescent, very soluble in water, soluble in alcohol. On exposure to light, ferric chloride and its solutions are partly reduced.

**Ferric chloride solution R1.** 1037801. A 105 g/l solution.

**Ferric chloride solution R2.** 1037802. A 13 g/l solution.

**Ferric chloride solution R3.** 1037803. Dissolve 2.0 g of ferric chloride R in ethanol R and dilute to 100.0 ml with the same solvent.

**Ferric chloride-ferricyanide-arsenite reagent.** 1037806. Immediately before use mix 10 ml of a 27 g/l solution of ferric chloride R in dilute hydrochloric acid R, 7 ml of potassium ferricyanide solution R, 3 ml of water R and 10 ml of sodium arsenite solution R.
Ferulic acid. C_{10}H_{10}O_{4}. (phenanthroline hydrochloride R
Assay
additional requirement.
Eleutherococcus (1419) complies with the following
Ferulic acid used in the assay of eleutherosides in
Faint yellow powder, freely soluble in methanol.
3-(4-Hydroxy-3-methoxyphenyl)propenoic acid.

3-one.

Fern chloro-sulphamic acid reagent. 1037804.
A solution containing 10 g/l of ferric chloride R and
16 g/l of sulphamic acid R.
Ferric nitrate. Fe(NO_{3})_{2}cdot9H_{2}O. (M, 404). 1106100.
[7782-61-8].
Content: minimum 99.0 per cent m/m of Fe(NO_{3})_{2}cdot9H_{2}O.
Light-purple crystals or crystalline mass, very soluble in
water.
Free acid: not more than 0.3 per cent (as HNO_{3}).
Ferric sulphate. Fe_{2}(SO_{4})_{3}cdotxH_{2}O. 1037900. [10028-22-5].
Iron(III) trisulphate hydrated.
A yellowish-white powder, very hygroscopic, decomposes in
air, slightly soluble in water and in alcohol.
Storage: protected from light.
Ferric sulphate pentahydrate. Fe_{2}(SO_{4})_{3}cdot5H_{2}O. (M, 489.9).
1153700. [142906-29-4].

Yellow or white powder.
Ferrocyphene. C_{26}H_{16}FeN_{6}. (Ferrocyphene.
White or yellowish powder.
Ferrocyanide.
Dicyanobis(1,10-phenanthroline)iron(II).
Ferrocyanide. Fe_{2}(CN)_{6}. (M, 556.1). 1153900.

White or almost white crystals, freely soluble in water and in alcohol.
Storage: protected from light.
Ferroin. 1038100. [14634-91-4].
Dissolve 0.7 g of ferrous sulphate R and 1.76 g of
phenantroline hydrochloride R in 70 ml of water R and
dilute to 100 ml with the same solvent.
Test for sensitivity. To 50 ml of dilute sulphuric acid R add
0.15 ml of osmium tetroxide solution R and 0.1 ml of the ferroin.
After the addition of 0.1 ml of 0.1 M ammonium and
cerium nitrate the colour changes from red to light blue.
Ferrous ammonium sulphate. Fe(NH_{4})_{2}(SO_{4})_{2}cdot6H_{2}O. (M, 392.2). 1038200. [7783-85-9].
Diammonium iron disulphate hexahydrate.
Pale bluish-green crystals or granules, freely soluble in
water, practically insoluble in alcohol.
Storage: protected from light.
Ferrous sulphate. 1038300. [7782-63-0].
See Ferrous sulphate (0083).
Ferrous sulphate solution R2. 1038301.
Dissolve 0.45 g of ferrous sulphate R in 50 ml of 0.1 M
hydrochloric acid and dilute to 100 ml with carbon
dioxide-free water R. Prepare immediately before use.
Ferulic acid. C_{10}H_{10}O_{4}. (M, 194.2). 1149500. [1135-24-6].
4-Hydroxy-3-methoxycinnamic acid.
3(4-Hydroxy-3-methoxyphenyl)propenoic acid.
Faint yellow powder, freely soluble in methanol.
mp: 172.9 °C to 173.9 °C.
Ferulic acid used in the assay of eleutherosides in
Eleutherococcus (1419) complies with the following
additional requirement.
Assay. Examine by liquid chromatography (2.2.29) as
prescribed in the monograph on Eleutherococcus (1419).
The content is not less than 99 per cent, calculated by the
normalisation procedure.

Fibrin blue. 1103400.
Mix 1.5 g of fibrin with 30 ml of a 5 g/l solution of indigo
carmine R in 1 per cent V/V dilute hydrochloric acid R.
Heat the mixture to 80 °C and maintain at this temperature
whilst stirring for about 30 min. Allow to cool. Filter.
Wash extensively by resuspension in 1 per cent V/V dilute
hydrochloric acid R and mixing for about 30 min; filter.
Repeat the washing operation three times. Dry at 50 °C.
Grind.
Fibrin congo red. 1038400.
Take 1.5 g of fibrin and leave overnight in 50 ml of a 20 g/l
solution of congo red R in alcohol (90 per cent V/V) R.
Filter, rinse the fibrin with water R and store under ether R.
Fibrinogen. 1038500. [9001-32-5].
See Human fibrinogen, freeze-dried (0024).
Fixing solution. 1122600.
To 250 ml of methanol R, add 0.27 ml of formaldehyde R
and dilute to 500.0 ml with water R.
Fixing solution for isolectric focusing in polyacrylamide
gel. 1138700.
A solution containing 35 g of sulphosalicylic acid R and
100 g of trichloroacetic acid R per litre of water R.
Flufenamic acid. C_{14}H_{10}F_{3}NO_{2}. (M, 281.2). 1106200.
[530-78-9]. 2-[3-(Trifluoromethyl)phenyl]amino]benzoic
acid.
Pale yellow, crystalline powder or needles, practically
insoluble in water, freely soluble in alcohol.
mp: 132 °C to 135 °C.
Flumazenil. 1149600. [78755-81-4].
See Flumazenil (1326).
Flunitrazepam. 1153800. [1622-62-4].
See Flunitrazepam (0717).
Fluoranthene. C_{16}H_{10}. (M, 202.3). 1038600. [206-44-0].
1,2-(1,8-Naphtylene)benzene. 1,2-Benzacenaphtene.
Yellow or yellowish-brown crystals.
bp: about 384 °C.
mp: 109 °C to 110 °C.
Fluorene. C_{12}H_{10}. (M, 166.2). 1127400. [86-73-7].
Diphenylenemethane.
White or almost white crystals, freely soluble in anhydrous
acetic acid, soluble in hot alcohol.
mp: 113 °C to 115 °C.
Fluorescamine. C_{17}H_{10}O_{4}. (M, 278.3). 1135800. [38342-12-9].
4-Phenylspiro[furan-2(3'H),1'(3'H)-
isobenzofuran]-3',3'-dione.
mp: 154 °C to 155 °C.
Fluorescein. C_{20}H_{12}O_{5}. (M, 332.3). 1106300. [2321-07-5].
3',6'-Dihydroxyisopropyl(isobenzofuran-1(3'H),9'-[9'H]xanthen]-
3-one.
An orange-red powder, practically insoluble in water, soluble
in warm alcohol, soluble in alkaline solutions. In solution,
fluorescein displays a green fluorescence.
mp: about 315 °C.
Fluorescein-conjugated rabies antiserum. 1038700.
Immunoglobulin fraction with a high rabies antibody titre, prepared from the sera of suitable animals that have been immunised with inactivated rabies virus; the immunoglobulin is conjugated with fluorescein isothiocyanate.

2-Fluoro-2-deoxy-D-glucose. C₇H₁₂O₅. (M, 182.2). 1113900. [86783-82-6].
A white or almost white crystalline powder.
mP: 174 °C to 176 °C.

Fluoroantimycin A₁. C₈H₁₂NO₆. (M, 187.2). 1038800. [70-34-8].
A white or almost white amorphous solid, soluble in water.

Formic acid, anhydrous. 4-dihydroxyphenyl)propanoic acid hydrochloride.
2-Fluoro-5-hydroxy-DL-tyrosine hydrochloride.
6-Fluorolevodopa hydrochloride. C₉H₁₁ClFNO₄. (M, 251.6). 1169300. [367-86-2].
A white or almost white crystalline powder.
mP: about 103 °C, determined at a pressure of 2 kPa.

Water: protected from light.

Storage.

Formic acid (0067)
See 35 per cent) (0826).

Formic acid. C₂H₂O₂. (M, 46.03). 1039000. [6696-41-9].
A colourless liquid, corrosive, miscible with water and with alcohol.

Distillation range: about 1.22.

Assay. Weigh accurately a conical flask containing 10 ml of water R, quickly add about 1 ml of the acid and weigh again. Add 50 ml of water R and titrate with 1 M sodium hydroxide, using 0.5 ml of phenolphthalein solution R as indicator.

1 ml of 1 M sodium hydroxide is equivalent to 46.03 mg of CH₂O₂.

Fructose. 1106400. [57-48-7].
See Fructose (0188).

Fuchsin, basic. 1039400. [632-99-5].
A mixture of rosinamide hydrochloride (C₁₇H₁₀ClN₂. 3H₂O, M, 337.9; Colour Index No. 42510; Schultz No. 780) and pararosaniline hydrochloride (C₁₇H₁₄ClN₂. 3H₂O, M, 323.8; Colour Index No. 42500; Schultz No. 779).

If necessary, purify in the following manner. Dissolve 1 g in 250 ml of dilute hydrochloric acid R. Allow to stand for 2 h at room temperature, filter and neutralise with dilute sodium hydroxide solution R and add 1 ml to 2 ml in excess. Filter the precipitate through a sintered-glass filter (40) (2.1.2) and wash with water R. Dissolve the precipitate in 70 ml of methanol R, previously heated to boiling, and add 300 ml of water R at 80 °C. Allow to cool to room temperature, filter and dry the crystals in vacuo.

Crystals with a greenish-bronze sheen, soluble in water and in alcohol.

Storage: protected from light.

Fuchsin solution, decolourised. 1039401.
Dissolve 0.1 g of basic fuchsin R in 60 ml of water R. Add a solution containing 1 g of anhydrous sodium sulphite R or 2 g of sodium sulphite R in 10 ml of water R. Slowly and with continuous shaking add 2 ml of hydrochloric acid R. Dilute to 100 ml with water R. Allow to stand protected from light for at least 12 h, decolourise with activated charcoal R and filter. If the solution becomes cloudy, filter before use. If on standing the solution becomes violet, decolourise again by adding activated charcoal R.

Test for sensitivity. To 1.0 ml add 1.0 ml of water R and 0.1 ml of alcohol-free alcohol R. Add 0.2 ml of a solution containing 0.1 g/l of formaldehyde (CH₂O, M, 30.0). A pale-pink colour develops within 5 min.

Storage: protected from light.

Fuchsin solution, decolourised R₁. 1039402.
To 1 g of basic fuchsin R add 100 ml of water R. Heat to 50 °C and allow to cool with occasional shaking. Allow to stand for 48 h, shake and filter. To 4 ml of the filtrate add 6 ml of hydrochloric acid R, mix and dilute to 100 ml with water R. Allow to stand for at least 1 h before use.

Fucose. C₅H₁₀O₅. (M, 164.2). 1039500. [110-17-8].
6-Deoxy-D-galactose.
A white or almost white powder, soluble in water and in alcohol.

Density (20 °C) : about 1.155 to 1.161.

Storage: in a dark place.

Fructose. 1106400. [57-48-7].
See Fructose (0188).

Fumaric acid. C₄H₂O₄. (M, 116.1). 1153200. [110-17-8].
(E)-Butenedioic acid.
White or almost white crystals, slightly soluble in water, soluble in alcohol, slightly soluble in acetone.

mp: about 300 °C.

Furfural. C₅H₄O₂. (M, 96.1). 1039600. [98-01-1].
2-Furaldehyde. 2-Furanecarbaldehyde.
A clear, colourless to brownish-yellow, oily liquid, miscible in 2-Furaldehyde. 2-Furanecarbaldehyde.

Distillation range: about 1.22.

Not less than 95 per cent distils between 159 °C and 163 °C.

Storage: in a dark place.
Galactose. C₆H₁₂O₆. (M₁ 180.2). 1039700. [59-23-4].

D(-)-Galactose.

A white or almost white, crystalline powder, freely soluble in water.

\[ \delta^D_25: +79 \text{ to } +81 \text{, determined on a 100 g/1 solution in water R containing about 0.05 per cent of NH}_3. \]

Gallic acid. C₇H₄O₅. H₂O. (M₁ 188.1). 1039800. [5995-86-8].

3,4,5-Trihydroxybenzoic acid monohydrate.

A crystalline powder or long needles, colourless or slightly yellow, soluble in water, freely soluble in hot water, in alcohol and in glycerol.

It loses its water of crystallisation at 120 °C and it melts at about 260 °C, with decomposition.

Chromatography. Examine as prescribed in the monograph on Bearberry leaf (1054); the chromatogram shows only one principal spot.

Gastric juice, artificial. 1039900.

Dissolve 2.0 g of sodium chloride R and dilute to 1000 ml with water R.

GC concentrical column. 1135100.

A commercially available system consisting of 2 concentrically arranged tubes. The outer tube is packed with a porous polymer mixture. The main application is the separation of gases.

Gelatin. 1040000. [9000-70-8].

See Gelatin (0330).

Gelatin, hydrolysed. 1040100.

Dissolve 50 g of gelatin R in 1000 ml of water R. Autoclave in saturated steam at 121 °C for 90 min and freeze dry.

Geraniol acetate. C₁₀H₂₀O₂. (M₁ 196.3). 1106500. [105-87-3].

(E)-3,7-Dimethylocta-2,6-dien-1-ol.

An oily liquid, slight odour of rose, practically insoluble in water, miscible with alcohol.

Geraniol used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Citronella oil (1609).

Storage: in an airtight container, protected from light

Ginsenoside Rb₁. C₄₂H₇₂O₁₄,2H₂O. (M₁ 1040200. [4562-36-1].

Glycoside of Digitalis purpurea L. 3β-[O(2,6-Dideoxy-β-d-ribo-hexopyranosyl)-1→4]-O(2,6-dideoxy-β-d-ribo-hexopyranosyl)-1→4]-2,6-dideoxy-β-d-ribo-hexopyranosyl]-1→4]-2,6-dideoxy-β-d-ribo-hexopyranosyl]-14,16β-di-dihydroxy-5β,14β-card-20(22)-enolide.

A white or almost white, crystalline powder, practically insoluble in water and in most common organic solvents, soluble in pyridine.

\[ \delta_{25}^{10}: +20 \text{ to } +24 \text{, determined on a 5 g/1 solution in a mixture of equal volumes of chloroform R and methanol R.} \]

Chromatography. Examine as prescribed in the monograph on Digitalis leaf (0117); the chromatogram shows only one principal spot.

Glucosamine hydrochloride. C₇H₁₄ClNO₅. (M₁ 215.6).


Crystals, soluble in water.
4.1.1. Reagents

Glucose. 1025700. [50-99-7].
See Anhydrous glucose (0177).

D-Glucuronic acid. C₉H₁₄O₅. (M 194.1). 1119700. [6555-12-3].
Content: minimum 96.0 per cent of C₆H₁₀O₇, calculated with reference to the substance dried in vacuo (2.2.32).
Soluble in water and in alcohol.

Glucose. 1025700. [50-99-7].
See Glucose (85 per cent) (0497).

Glyceraldehyde. C₃H₆O. (M 60.09). 1098300. [111-30-8].

Glycerol (85 per cent). 1040500. [56-81-5].
See Glycerol (0496).

Glycylglycine. C₆H₁₂N₂O₄. (M 126.2). 1149700. [6152-51-8].

Glycine. 1040700. [56-40-6].
See Glycine (0614).

Glycolic acid. C₂H₂O₂. (M 44.05). 1040800. [79-14-1].
2-Hydroxyacetic acid.
Crystals, soluble in water, in acetone, and in methanol.
mp: about 80 °C.

Glycyrrhetinic acid. 12,13-Didehydro-3β-hydroxy-11-oxo-olean-30-oic acid.
A mixture of α- and β-glycyrrhetinic acids in which the β-isomer is predominant.
A white or yellowish-brown powder, practically insoluble in water, soluble in ethanol and in glacial acetic acid.
[n]₂⁰: +145 to +155, determined on a 10.0 g/1 solution in ethanol R.

Chromatography. Examine by thin-layer chromatography (2.2.27) using silica gel GF₂₅₄ as the coating substance; prepare the slurry using a 0.25 per cent solution of phosphoric acid R. Apply to the plate 5 µl of a 5 g/1 solution of the glycyrrhetic acid in a mixture of equal volumes of chloroform R and methanol R. Develop over a path of 10 cm using a mixture of 5 volumes of methanol R and 95 volumes of chloroform R. Examine the chromatogram in ultraviolet light at 254 nm. The chromatogram shows a dark spot (Rf about 0.3) corresponding to β-glycyrrhetic acid and a smaller spot (Rf about 0.5) corresponding to α-glycyrrhetic acid. Spray with anisaldehyde solution R and heat at 100 °C to 105 °C for 10 min. Both spots are coloured bluish-violet. Between them a smaller bluish-violet spot may be present.

A white or almost white powder, practically insoluble in water, soluble in ethanol, sparingly soluble in methylene chloride.

Glyoxal. 1040400. [56-86-0].
See Glutamic acid (0750).

Glyceraldehyde. C₃H₆O. (M 60.09). 1098300. [111-30-8].

Glycerol (85 per cent). 1040500. [56-81-5].
See Glycerol (0496).

Glycerol R1. 1040501.
Glycerol complying with the monograph Glycerol (0496) and free from diethyleneglycol when examined as described in the test for Impurity A and related substances in that monograph.

Glycerol (85 per cent). 1040600. See Glycerol (85 per cent) (0497).

Glycerol (85 per cent) R1. 1040601.
Glycerol complying with the monograph Glycerol 85 per cent (0497) and free from diethyleneglycol when examined as described in the test for Impurity A and related substances in that monograph.

Glyceraldehyde. C₃H₆O. (M 60.09). 1098300. [111-30-8].

α-Monocaprin. 1-Monodecanoyl-rac-glycerol.
Content: about 99 per cent.

Glycerol 1-octanoate. C₁₅H₂₆O₄. (M 218.3). 1169500. [502-54-5]. (2RS)-2,3-Dihydroxypropyl octanoate.
α-Monocaprylin. 1-Monoctanoyl-rac-glycerol.
Content: about 99 per cent.

Glycidol. C₅H₁₀O₃. (M 74.1). 1127800. [556-52-5].
A slightly viscous liquid, miscible with water.
[n]₂⁰: +1.115.
α: about 1.432.

Chromatography. Examine by thin-layer chromatography (2.2.27) using silica gel GF₂₅₄ as the coating substance; prepare the slurry using a 0.25 per cent solution of phosphoric acid R. Apply to the plate 5 µl of a 5 g/1 solution of the glycyrrhetic acid in a mixture of equal volumes of chloroform R and methanol R. Develop over a path of 10 cm using a mixture of 5 volumes of methanol R and 95 volumes of chloroform R. Examine the chromatogram in ultraviolet light at 254 nm. The chromatogram shows a dark spot (Rf about 0.3) corresponding to β-glycyrrhetic acid and a smaller spot (Rf about 0.5) corresponding to α-glycyrrhetic acid. Spray with anisaldehyde solution R and heat at 100 °C to 105 °C for 10 min. Both spots are coloured bluish-violet. Between them a smaller bluish-violet spot may be present.

A white or almost white powder, practically insoluble in water, soluble in ethanol, sparingly soluble in methylene chloride.

White or almost white crystals, soluble in hot alcohol.
mp: about 200 °C.

Glyoxal solution. 1098400. [107-22-2].
Contains about 40 per cent (m/m) glyoxal.
Assay. In a ground-glass stoppered flask place 1.000 g of glyoxal solution, 20 ml of a 70 g/1 solution of hydroxylamine hydrochloride R and 50 ml of water R. Allow to stand for 30 min and add 1 ml of methyl red mixed solution R and titrate with 1 M sodium hydroxide until the colour changes from red to green. Carry out a blank titration.
1 ml of 1 M sodium hydroxide is equivalent to 29.02 mg of glyoxal (C₅H₈O₂).

Gonadotrophin, chorionic. 1041100. [9002-61-3].
See Chorionic gonadotrophin (0498).

Gonadotrophin, serum. 1041200.
See Equine serum gonadotrophin for veterinary use (0719).
Guaiacol. C₇H₈O₂. (M, 124.1). 1148300. [90-05-1].
2-Methoxyphenol. 1-Hydroxy-2-methoxybenzene.
Crystalline mass or colourless or yellowish liquid, hygroscopic, slightly soluble in water, very soluble in methylene chloride, freely soluble in alcohol.
bp: about 205 °C.
mp: about 28 °C.
Guaiacum resin. 1041400.
Resin obtained from the heartwood of Guaiacum officinale L. and Guaiacum sanctum L.
Reddish-brown or greenish-brown, hard, glassy fragments; fracture shiny.

Guaiazulene. C₁₅H₁₈. (M, 198.3). 1041500. [489-84-9].
1,4-Dimethyl-7-isopropylazulene.
Dark-blue crystals or blue liquid, very slightly soluble in 1,4-Dimethyl-7-isopropylazulene.
mp: about 30 °C.

Guanidine hydrochloride. CH₅N₅HCl. (M, 95.5). 1098500. [50-01-1].
Crystalline powder, freely soluble in water and in alcohol.

Guaiacol. C₇H₈O₂. (M, 124.1). 1148300. [90-05-1].
2-Methoxyphenol. 1-Hydroxy-2-methoxybenzene.

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Guaiacol. C₇H₈O₂. (M, 124.1). 1148300. [90-05-1].
2-Methoxyphenol. 1-Hydroxy-2-methoxybenzene.

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2-Methoxyphenol. 1-Hydroxy-2-methoxybenzene.

Guaiacol. C₇H₈O₂. (M, 124.1). 1148300. [90-05-1].
2-Methoxyphenol. 1-Hydroxy-2-methoxybenzene.

Guaiacol. C₇H₈O₂. (M, 124.1). 1148300. [90-05-1].
2-Methoxyphenol. 1-Hydroxy-2-methoxybenzene.
α-Hexachlorocyclohexane. \( \text{C}_ {16} \text{H}_{12} \text{Cl}_6 \) \((M, 290.8)\). 1128300. [319-84-6].
bp: about 288 °C.
mp: about 158 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

β-Hexachlorocyclohexane. \( \text{C}_ {16} \text{H}_{12} \text{Cl}_6 \) \((M, 290.8)\). 1128400. [319-85-7].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

δ-Hexachlorocyclohexane. \( \text{C}_ {16} \text{H}_{12} \text{Cl}_6 \) \((M, 290.8)\). 1128500. [319-86-8].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Hexacosane. \( \text{C}_{26} \text{H}_{54} \). (cyclohexane) may be used.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Histamine dihydrochloride. 1042800. [56-92-8].
See Histamine dihydrochloride (0143).

Histamine phosphate. 1042900. [23297-93-0].
See Histamine phosphate (0144).

Histamine solution. 1042901.
A 9 g/l solution of sodium chloride \( \text{R} \) containing 0.1 µg per millilitre of histamine base (as the phosphate or dihydrochloride).

Histidine monohydrochloride. \( \text{C}_{13} \text{H}_{22} \text{ClN}_3 \text{O}_2 \text{H}_2 \text{O} \). \((M, 209.6)\). 1043000. [12333-71-1]. (R,S)-2-Amino-3-(imidazol-4-yl)propionic acid hydrochloride monohydrate.
A crystalline powder or colourless crystals, soluble in water.
mp: about 250 °C, with decomposition.
Chromatography. Examine as prescribed in the monograph on Histamine dihydrochloride (0143); the chromatogram shows only one principal spot.

Holmium oxide. \( \text{Ho}_2 \text{O}_3 \) \((M, 377.9)\). 1043100. [12055-62-8].
Diholmium trioxide.
A yellowish powder, practically insoluble in water.

Holmium perchlorate solution. 1043101.
A 40 g/l solution of holmium oxide \( \text{R} \) in a solution of perchloric acid \( \text{R} \) containing 141 g/l of HClO4.

Di-Homocysteine. \( \text{C}_ {16} \text{H}_{18} \text{NO}_2 \text{S} \) \((M, 153.2)\). 1136100. [454-29-5]. (2R,S)-2-Amino-4-sulphanylbutanoic acid.
A white or almost white, crystalline powder.
mp: about 232 °C.

L-Homocysteine thiolactone hydrochloride. \( \text{C}_ {16} \text{H}_{15} \text{N} \) \((M, 162.1)\). 1042400. [999-97-3].
A clear, colourless liquid.
\( d_{20}^\text{g} \): about 0.78.
\( n_\text{D}^{20} \): about 1.408.
bp: about 125 °C.
Storage: in an airtight container.

Hexamethyldisilazane. \( \text{C}_ {16} \text{H}_{32} \text{NSi}_2 \) \((M, 161.4)\). 1042400. [999-97-3].
A clear, colourless liquid.
\( d_{20}^\text{g} \): about 0.78.
\( n_\text{D}^{20} \): about 1.408.
bp: about 125 °C.
Storage: in an airtight container.

Hexamethylenetetramine. \( \text{C}_ {16} \text{H}_{14} \text{N}_6 \) \((M, 140.2)\). 1042500. [110-97-0]. Hexamine. 1,3,5,7-Tetra-azatricyclc [3.3.1.1^3,7]decane.
A colourless, crystalline powder, very soluble in water.

Hexane. \( \text{C}_ {16} \text{H}_{16} \) \((M, 86.2)\). 1042600. [110-54-3].
A colourless, flammable liquid, practically insoluble in water, miscible with ethanol.
\( d_{20}^\text{g} \): 0.659 to 0.663.
\( n_\text{D}^{20} \): 1.375 to 1.376.
Distillation range (2.2.11). Not less than 95 per cent distils between 67 °C and 69 °C.

Hexane used in spectrophotometry complies with the following additional test.
Minimum transmittance (2.2.25), determined using water \( \text{R} \) as compensation liquid: 97 per cent from 260 nm to 420 nm.

Hexylamine. \( \text{C}_ {16} \text{H}_{15} \text{N} \) \((M, 101.2)\). 1042700. [111-26-2].
Hexanamine.
A colourless liquid, slightly soluble in water, soluble in alcohol.
\( d_{20}^\text{g} \): about 0.766.
\( n_\text{D}^{20} \): about 1.418.
bp: 127 °C to 131 °C.

Histamine dihydrochloride. 1042800. [56-92-8].
See Histamine dihydrochloride (0143).

Histamine phosphate. 1042900. [23297-93-0].
See Histamine phosphate (0144).

Histamine solution. 1042901.
A 9 g/l solution of sodium chloride \( \text{R} \) containing 0.1 µg per millilitre of histamine base (as the phosphate or dihydrochloride).

Histidine monohydrochloride. \( \text{C}_ {16} \text{H}_{22} \text{ClN}_3 \text{O}_2 \text{H}_2 \text{O} \). \((M, 209.6)\). 1043000. [12333-71-1]. (R,S)-2-Amino-3-(imidazol-4-yl)propionic acid hydrochloride monohydrate.
A crystalline powder or colourless crystals, soluble in water.
mp: about 250 °C, with decomposition.
Chromatography. Examine as prescribed in the monograph on Histamine dihydrochloride (0143); the chromatogram shows only one principal spot.

Holmium oxide. \( \text{Ho}_2 \text{O}_3 \) \((M, 377.9)\). 1043100. [12055-62-8].
Diholmium trioxide.
A yellowish powder, practically insoluble in water.

Holmium perchlorate solution. 1043101.
A 40 g/l solution of holmium oxide \( \text{R} \) in a solution of perchloric acid \( \text{R} \) containing 141 g/l of HClO4.

2,2′,2″,6′,6″-Hexafluoro-1,1-dimethyl-1,3,5-trimethylene	riphenol. \( \text{C}_{14} \text{H}_{12} \text{F}_6 \text{O} \). \((M, 364.2)\). 1128300. [319-84-6].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

2,2′,2″,6′,6″-Hexafluoro-1,1-dimethyl-1,3,5-trimethylene	riphenol. \( \text{C}_{14} \text{H}_{12} \text{F}_6 \text{O} \). \((M, 364.2)\). 1128300. [319-84-6].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

2,2′,2″,6′,6″-Hexafluoro-1,1-dimethyl-1,3,5-trimethylene	riphenol. \( \text{C}_{14} \text{H}_{12} \text{F}_6 \text{O} \). \((M, 364.2)\). 1128300. [319-84-6].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

2,2′,2″,6′,6″-Hexafluoro-1,1-dimethyl-1,3,5-trimethylene	riphenol. \( \text{C}_{14} \text{H}_{12} \text{F}_6 \text{O} \). \((M, 364.2)\). 1128300. [319-84-6].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

2,2′,2″,6′,6″-Hexafluoro-1,1-dimethyl-1,3,5-trimethylene	riphenol. \( \text{C}_{14} \text{H}_{12} \text{F}_6 \text{O} \). \((M, 364.2)\). 1128300. [319-84-6].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.
Assay. Examine by liquid chromatography (2.2.29) as prescribed in the monograph on Goldenseal rhizome (1831). The content is not less than 98 per cent, calculated by the normalisation procedure.

Hydrazine. H₄N₂ (Mₐ 32.05). 1136300. [302-01-2]. Diazane. A slightly oily liquid, colourless, with a strong odour of ammonia, miscible with water. Dilute solutions in water are commercially available.

Caution: toxic and corrosive.

D: about 1.470.
bp: about 113 °C.
mp: about 1.5 °C.

Hydrazine sulphate. H₄N₂O₄S (Mₐ 130.1). 1043400. [10034-93-2].

Colourless crystals, sparingly soluble in cold water, soluble in hot water (50 °C) and freely soluble in boiling water, practically insoluble in alcohol.

Arsenic (2.4.2). 1.0 g complies with limit test A (1 ppm).

Sulphated ash (2.4.14): maximum 0.1 per cent.

Hydriodic acid. HI. (Mₐ 1043500. [74-90-8].

Prepare by distilling hydriodic acid over red phosphorus, passing carbon dioxide R or nitrogen R through the apparatus during the distillation. Use the colourless or almost colourless, constant-boiling mixture (55 per cent to 58 per cent of HI) distilling between 126 °C and 127 °C. Place the acid in small, amber, glass-stoppered bottles previously flushed with carbon dioxide R or nitrogen R, seal with paraffin.

Storage: in a dark place.

Hydrobromic acid, 30 per cent. 1098700. [10035-10-6].

30 per cent hydrobromic acid in glacial acetic acid R.

Degas with caution the contents before opening.

Hydrobromic acid, dilute. 1098701.

Place 5.0 ml of 30 per cent hydrobromic acid R in amber vials equipped with polyethylene stoppers. Seal under argon R and store in the dark. Add 5.0 ml of glacial acetic acid R immediately before use. Shake.

Storage: in the dark.

Hydrobromic acid, 47 per cent. 1118900.

A 47 per cent m/m solution of hydrobromic acid in water R.

Hydrobromic acid, dilute R1. 1118901.

Contains 7.9 g/l of HBr.

Dilute 16.81 g of 47 per cent hydrobromic acid R in water R and dilute to 1000 ml with the same solvent.

Hydrochloric acid. 1043500. [7647-01-0].

See Concentrated hydrochloric acid (0002).

2 M Hydrochloric acid. 3001700.

Dilute 206.0 g of hydrochloric acid R to 1000.0 ml with water R.

3 M Hydrochloric acid. 3001600.

Dilute 309.0 g of hydrochloric acid R to 1000.0 ml with water R.

6 M Hydrochloric acid. 3001500.

Dilute 618.0 g of hydrochloric acid R to 1000.0 ml with water R.

Hydrochloric acid R1. 1043501.

Contains 250 g/l of HCl.

Dilute 70 g of hydrochloric acid R to 100 ml with water R.

Hydrochloric acid, brominated. 1043507.

To 1 ml of bromine solution R add 100 ml of hydrochloric acid R.

Hydrochloric acid, dilute. 1043503.

Contains 73 g/l of HCl.

Dilute 20 g of hydrochloric acid R to 100 ml with water R.

Hydrochloric acid, dilute, heavy metal-free. 1043509.

Complies with the requirements prescribed for dilute hydrochloric acid R and with the following maximum contents of heavy metals:

As: 0.005 ppm;
Cd: 0.003 ppm;
Cu: 0.003 ppm;
Fe: 0.05 ppm;
Hg: 0.005 ppm;
Ni: 0.004 ppm;
Pb: 0.001 ppm;
Zn: 0.005 ppm.

Hydrochloric acid, dilute R1. 1043504.

Contains 0.37 g/l of HCl.

Dilute 1.0 ml of dilute hydrochloric acid R to 200.0 ml with water R.

Hydrochloric acid, dilute R2. 1043505.

Dilute 30 ml of 1 M hydrochloric acid to 1000 ml with water R; adjust to pH 1.6 ± 0.1.

Hydrochloric acid, ethanolic. 1043506.

Dilute 5.0 ml of 1 M hydrochloric acid to 500.0 ml with alcohol R.

Hydrochloric acid, heavy metal-free. 1043510.

Complies with the requirements prescribed for hydrochloric acid R and with the following maximum contents of heavy metals:

As: 0.005 ppm;
Cd: 0.003 ppm;
Cu: 0.003 ppm;
Fe: 0.05 ppm;
Hg: 0.005 ppm;
Ni: 0.004 ppm;
Pb: 0.001 ppm;
Zn: 0.005 ppm.

Hydrochloric acid, lead-free. 1043508.

Complies with the requirements prescribed for hydrochloric acid R and with the following additional test.

Lead: maximum 20 ppb of Pb determined by atomic emission spectrometry (2.2.22, Method I).

Test solution. In a quartz crucible evaporate 200 g of the acid to be examined almost to dryness. Take up the residue in 5 ml of nitric acid prepared by sub-boiling distillation of nitric acid R and evaporate to dryness. Take up the residue in 5 ml of nitric acid prepared by sub-boiling distillation of nitric acid R.
4.1.1. Reagents

Reference solutions. Prepare the reference solutions using lead standard solution (0.1 ppm Pb) R diluted with nitric acid prepared by sub-boiling distillation of nitric acid R. Measure the emission intensity at 220.35 nm.

Hydrocortisone acetate. 1098800. [50-03-3]. See Hydrocortisone acetate (0334).

Hydrofluoric acid. HF. (M, 20.01). 1043600. [7664-39-3].
Content: minimum 40.0 per cent m/m of HF. A clear, colourless liquid.
Residue on ignition. Not more than 0.05 per cent m/m. Evaporate the hydrofluoric acid in a platinum crucible and gently ignite the residue to constant mass.
Assay. Weigh accurately a glass-stoppered flask containing 50.0 ml of 1 M sodium hydroxide. Introduce 2 g of the hydrofluoric acid and weigh again. Titrate the solution with 0.5 M sulphuric acid, using 0.5 ml of phenolphthalein solution R as indicator.
1 ml of 1 M sodium hydroxide is equivalent to 20.01 mg of HF.
Storage: in a polyethylene container.

Content: minimum 99.95 per cent V/V of H2.

Hydrogen peroxide solution, dilute. 1043800. [7722-84-1]. See Hydrogen peroxide solution (3 per cent) (0397).

Hydrogen peroxide solution, strong. 1043900. [7722-84-1]. See Hydrogen peroxide solution (3 per cent) (0397).

Hydrogen sulphide solution. 1136400.
A recently prepared solution of hydrogen sulphide R in water R. The saturated solution contains about 0.4 per cent to 0.5 per cent of H2S at 20 °C.

Content: minimum 99.7 per cent V/V of H2S.

Fine, colourless or white or almost white needles, darkening on exposure to air and light, soluble in water and in alcohol.
mp: about 173 °C.
Storage: protected from light and air.

Hydroquinone solution. 1044101.
Dissolve 0.5 g of hydroquinone R in water R, add 20 μl of sulphuric acid R and dilute to 50 ml with water R.


mp: 214 °C to 215 °C.

White or almost white powder, freely soluble in methanol.
Content: minimum 98.0 per cent.

mp: about 257 °C.

A white or almost white powder.
mp: about 236 °C, with decomposition

Needles or platelets, very slightly soluble in water, freely soluble in alcohol.
mp: about 314 °C, with decomposition.

Hydroxyamine hydrochloride. NH2ClO. (M, 69.5). 1044300. [5470-11-1].
A white or almost white crystalline powder, very soluble in water, soluble in alcohol.

Hydroxyamine hydrochloride solution R2. 1044304.
Dissolve 2.5 g of hydroxyamine hydrochloride R in 4.5 ml of hot water R and add 40 ml of alcohol R and 0.4 ml of bromophenol blue solution R2. Add 0.5 M alcoholic potassium hydroxide until a greenish-yellow colour is obtained. Dilute to 50.0 ml with alcohol R.

Hydroxyamine solution, alcoholic. 1044301.
Dissolve 3.5 g of hydroxyamine hydrochloride R in 95 ml of alcohol (60 per cent V/V) R, add 0.5 ml of a 2 g/l solution of methyl orange R in alcohol (60 per cent V/V) R and sufficient 0.5 M potassium hydroxide in alcohol (60 per cent V/V) R to give a pure yellow colour. Dilute to 100 ml with alcohol (60 per cent V/V) R.

Hydroxyamine solution, alkaline. 1044302.
Immediately before use, mix equal volumes of a 139 g/l solution of hydroxyamine hydrochloride R and a 150 g/l solution of sodium hydroxide R.

Hydroxyamine solution, alkaline R1. 1044303.
Solution A. Dissolve 12.5 g of hydroxyamine hydrochloride R in methanol R and dilute to 100 ml with the same solvent.
Solution B. Dissolve 12.5 g of sodium hydroxide R in methanol R and dilute to 100 ml with the same solvent.
Mix equal volumes of solution A and solution B immediately before use.

Acicular crystals, freely soluble in water, in acetone and in alcohol.
mp: about 32 °C.


2-Hydroxypropylβ-cyclodextrin for chromatography R. 1146000.
Beta-cyclodextrin modified by the bonding of (R) or (RS) propylene oxide groups on the hydroxyl groups.

Hydroxypropyl-β-cyclodextrin. 1128600. [94035-02-6]. See Hydroxypropylbetadex (1804).

See the information section on general monographs (cover pages)
Hydroxyquinoline. \( \text{C}_6\text{H}_8\text{NO} \). (M, 145.2). 1044600.

A white or slightly yellowish, crystalline powder, slightly soluble in water, freely soluble in acetone, in alcohol and in dilute mineral acids.

mp: about 75 °C.

**Sulphated ash (2.4.14):** maximum 0.05 per cent.

**12-Hydroxysestearic acid.** \( \text{C}_{18}\text{H}_{36}\text{O}_3 \).

White or almost white powder.

mp: 71 °C to 74 °C.

5-Hydroxyuracil. \( \text{C}_4\text{H}_4\text{N}_2\text{O}_3 \).

A white or almost white, crystalline powder.

mp: about 310 °C, with decomposition.

**Chromatography.** Examined as prescribed in the monograph on Fluourouracil (0611), the chromatogram shows a principal spot with an \( R_f \) of about 0.3.

**Storage:** in an airtight container.

Hyoscine hydrobromide. 1044800. [6533-68-2].

See Hyoscyamine hydrobromide (0106).

Hyoscyamine sulphate. 1044900. [620-61-1].

See Hyoscyamine sulphate (0501).

Hypericin. \( \text{C}_{10}\text{H}_{12}\text{N}_4\text{O}_5 \). (M, 254.4). 1149800.

A blue or violet-blue powder or blue granules with a coppery lustre, sparingly soluble in water, practically insoluble in alcohol. It is precipitated from an aqueous solution by sodium chloride.

**Indigo carmine solution.** 1045601.

To a mixture of 10 ml of hydrochloric acid \( R \) and 990 ml of 200 g/l nitrogen-free sulphuric acid \( R \) add 0.2 g of indigo carmine \( R \).

The solution complies with the following test.

Add 10 ml to a solution of 1.0 mg of potassium nitrate \( R \) in 10 ml of water \( R \), rapidly add 20 ml of nitrogen-free sulphuric acid \( R \) and heat to boiling. The blue colour is discharged within 1 min.

**Indigo carmine solution R1.** 1045602.

Dissolve 4 g of indigo carmine \( R \) in about 900 ml of water \( R \) added in several portions. Add 2 ml of sulphuric acid \( R \) and dilute to 1000 ml with water \( R \).

**Standardisation.** Place in a 100 ml conical flask with a wide neck 10.0 ml of nitrate standard solution (100 ppm \( \text{NO}_3 \)). 10 ml of water \( R \), 0.05 ml of the indigo carmine solution R1, and then in a single addition, but with caution, 30 ml of sulphuric acid \( R \). Titrate the solution immediately, using the indigo carmine solution R1, until a stable blue colour is obtained.

The number of millilitres used, \( n \), is equivalent to 1 mg of \( \text{NO}_3 \).

Indometacin. 1101500. [53-86-1].

See Indometacin (0092).

Inosine. \( \text{C}_{10}\text{H}_{12}\text{N}_4\text{O}_5 \). (M, 268.2). 1169900.

A white or slightly yellowish, crystalline powder, slightly soluble in water, sparingly soluble in boiling water, soluble in dilute acids and in dilute alkali hydroxide solutions, decomposes without melting at about 150 °C.

**Chromatography.** Examine as prescribed in the monograph on Mercaptopurine (0096); the chromatogram shows only one principal spot.

Imidazole. \( \text{C}_2\text{H}_4\text{N}_2 \). (M, 68.1). 1045400.

A white or almost white, crystalline powder, soluble in water and in alcohol.

mp: about 90 °C.

Iminodibenzyl. \( \text{C}_9\text{H}_8\text{N}_2 \). (M, 195.3). 1045500. [494-19-9].

10,11-Dihydrodibenz[b,\( \beta \)apine.

A pale yellow, crystalline powder, practically insoluble in water, freely soluble in acetone.

mp: about 106 °C.

Indigo carmine. \( \text{C}_{58}\text{H}_{84}\text{N}_2\text{O}_2\text{S}_2 \). (M, 466.3). 1045600.

Schultz No. 1309.

Colour Index No. 73015.

3,3’-Dioxy-2,2’-bisindolylidene-5,5’-disulphonate disodium. E 132.

It usually contains sodium chloride.

A blue or violet-blue powder or blue granules with a coppery lustre, sparingly soluble in water, practically insoluble in alcohol. It is precipitated from an aqueous solution by sodium chloride.

## 4. Reagents

General Notices (1) apply to all monographs and other texts
4.1.1. Reagents

Iodine pentoxide, recrystallised.

Dissolve 0.100 g in 50 ml of dilute hydrochloric acid R and dilute to 1000 ml with water R. Prepare immediately before use.

Iodine solution R4. 1045806.

Dissolve 14 g of iodine R in 100 ml of a 400 g/l solution of potassium iodide R, add 1 ml of dilute hydrochloric acid R and dilute to 1000 ml with water R.

Storage: protected from light.

Iodine solution, alcoholic. 1045804.

A 10 g/l solution in alcohol R.

Storage: protected from light.

Iodine solution, chloroformic. 1045805.

A 5 g/l solution in chloroform R.

Storage: protected from light.

Iodine-123 and ruthenium-106 spiking solution. 1166700.

Mix 3.5 ml of an 18.5 kBq/ml solution of ruthenium-106 in the form of ruthenium trichloride in a mixture of equal volumes of glacial acetic acid R and water R with 200 µl of a 75 kBq/ml solution of iodine-123 in the form of sodium iodide in water R.

Iodine bromide. Br. (M, 206.8). 1045900. [7789-33-5].

Bluish-black or brownish-black crystals, freely soluble in water, in alcohol and in glacial acetic acid.

bp: about 116 °C.

mp: about 40 °C.

Storage: protected from light.

Iodine bromide solution. 1045901.

Dissolve 20 g of iodine bromide R in glacial acetic acid R and dilute to 1000 ml with the same solvent.

Storage: protected from light.

Iodine chloride. ICl. (M, 162.4). 1143000. [7790-99-0].

Black crystals, soluble in water, in acetic acid and in alcohol.

bp: about 97.4 °C.

Iodine chloride solution. 1143001.

Dissolve 1.4 g of iodine chloride R in glacial acetic acid R and dilute to 100 ml with the same acid.

Storage: protected from light.


Content: minimum 99.5 per cent of I₂O₅.

A white or almost white, crystalline powder, or white or greyish-white granules, hygroscopic, very soluble in water forming HIO₃.

Stability on heating. Dissolve 2 g, previously heated for 1 h at 200 °C, in 50 ml of water R. A colourless solution is obtained.

Assay. Dissolve 0.100 g in 50 ml of water R, add 3 g of potassium iodide R and 10 ml of dilute hydrochloric acid R. Titrate the liberated iodine with 0.1 M sodium thiosulphate, using 1 ml of starch solution R as indicator.

1 ml of 0.1 M sodium thiosulphate is equivalent to 2.782 mg of I₂O₅.

Storage: in an airtight container, protected from light.

Iodoacetic acid. C₃H₅IO₂. (M, 185.9). 1107000. [64-69-7].

Colourless or white or almost white crystals, soluble in water and in alcohol.

mp: 82 °C to 83 °C.


A white or slightly yellow, crystalline powder, slightly soluble in water, soluble in alcohol.

mp: about 160 °C.

Chromatography. Examine by thin-layer chromatography (2.2.27), using cellulose for chromatography F₂₅₄ as the coating substance. Apply to the plate 20 µl of a solution of the 2-Iodobenzoic acid, prepared by dissolving 40 mg in 4 ml of 0.1 M sodium hydroxide and diluting to 10 ml with water R. Develop over a path of about 12 cm using as the mobile phase the upper layer obtained by shaking together 20 volumes of water R, 40 volumes of glacial acetic acid R and 40 volumes of toluene R. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The chromatogram shows only one principal spot.

3-Iodobenzylammonium chloride. C₇H₅ClIN. (M, 269.5). 1168000. [3718-88-5]. 1-(3-Iodophenyl)methanaminium hydrochloride. 1-(3-Iodophenyl)methanaminium chloride. m-Iodobenzylamine hydrochloride.

White or almost white crystals.

mp: 188 °C to 190 °C.

Iodoethane. C₂H₃I. (M, 155.9). 1099100. [75-03-6].

Colourless or slightly yellowish liquid, darkening on exposure to air and light, miscible with alcohol and most organic solvents.

δ[H₂]: about 1.95.

n[D₂]: about 1.513.

bp: about 72 °C.

Storage: in an airtight container.


A white or almost white, crystalline powder, sparingly soluble in water.

mp: about 170 °C.

Water (2.5.12): 9 per cent to 13 per cent, determined on 1.000 g.

Chromatography. Examine by thin-layer chromatography (2.2.27), using cellulose for chromatography F₂₅₄R as the coating substance. Apply to the plate 20 µl of a solution of the 2-Iodohippuric acid, prepared by dissolving 40 mg in 4 ml of 0.1 M sodium hydroxide and diluting to 10 ml with water R. Develop over a path of about 12 cm using as the mobile phase the upper layer obtained by shaking together 20 volumes of water R, 40 volumes of glacial acetic acid R and 40 volumes of toluene R. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The chromatogram shows only one principal spot.

Iodoplatinate reagent. 1046300.

To 3 ml of a 100 g/l solution of chloroplatinic acid R add 97 ml of water R and 100 ml of a 60 g/l solution of potassium iodide R.

Storage: protected from light.
Iodosulphurous reagent. 1046400.
The apparatus, which must be kept closed and dry during the preparation, consists of a 3000 ml to 4000 ml round-bottomed flask with three inlets for a stirrer and a thermometer and fitted with a drying tube. To 700 ml of anhydrous pyridine R and 700 ml of ethyleneglycol monomethyl ether R add, with constant stirring, 220 g of finely powdered iodine R, previously dried over diphosphorus pentoxide R. Continue stirring until the iodine has completely dissolved (about 30 min). Cool to – 10 °C, and add quickly, still stirring, 190 g of sulphur dioxide R. Do not allow the temperature to exceed 30 °C. Cool.

Standardisation. Add about 20 ml of anhydrous methanol R to a titration vessel and titrate to the end-point with the iodosulphurous reagent (2.5.12). Introduce in an appropriate form a suitable amount of water R, accurately weighed, and repeat the determination of water. Calculate the water equivalent in milligrams per millilitre of iodosulphurous reagent.
The minimum water equivalent is 3.5 mg of water per millilitre of reagent.
Work protected from humidity. Standardise immediately before use.
Storage: in a dry container.

5-Iodosulphurous reagent. 1046500. [696-07-1].
5-Iodo-1H,3H-pyrimidin-2,4-dione.
mp: about 276 °C, with decomposition.
Chromatography. Examine as prescribed in the monograph on Idoxuridine (0669), applying 5 μl of a 0.25 g/l solution. The chromatogram obtained shows only one principal spot.

Ion-exclusion resin for chromatography. 1131000.
A resin with sulphonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene.

Ion-exchange resin, strongly acidic. 1085400.
A resin in protonated form with sulphonic acid groups attached to a lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene. It is available as spherical beads; unless otherwise prescribed, the particle size is 0.3 mm to 1.2 mm.
Capacity. 4.5 mmol to 5 mmol per gram, with a water content of 50 per cent to 60 per cent.
Preparation of a column. Unless otherwise prescribed, use a tube with a fused-in sintered glass disc having a length of 400 mm, an internal diameter of 20 mm and a filling height of about 200 mm. Introduce the resin, mixing it with water R until 50 ml requires not more than 0.05 ml of 0.1 M sodium hydroxide for neutralisation, using 0.1 ml of methyl orange solution R as indicator.
If the resin is in its sodium form or if it requires regeneration, pass about 100 ml of a mixture of equal volumes of hydrochloric acid R1 and water R slowly through the column and then wash with water R as described above.
Iron. Fe. (A, 55.85). 1046600. [7439-89-6].
Grey powder or wire, soluble in dilute mineral acids.
Iron salicylate solution. 1046700.
Dissolve 0.1 g of ferric ammonium sulphate R in a mixture of 2 ml of dilute sulphuric acid R and 48 ml of water R and dilute to 100 ml with water R. Add 50 ml of a 11.5 g/l solution of sodium salicylate R, 10 ml of dilute acetic acid R, 80 ml of a 136 g/l solution of sodium acetate R and dilute to 500 ml with water R. The solution should be recently prepared.
Storage: in an airtight container, protected from light.

Isatin. C9H6N2O2. (M, 192.3).
MP: about 200 °C, with partial sublimation.
Sulphated ash (2.4.14): maximum 0.2 per cent.
Isatin reagent. 1046801.
Dissolve 6 mg of ferric sulphate R in 8 ml of water R and add cautiously 50 ml of sulphuric acid R. Add 6 mg of isatin R and stir until dissolved.
The reagent should be pale yellow, but not orange or red.

Isoamyl alcohol. C8H16O. (M, 122.23).
3-Methylbutan-1-ol.
A colourless liquid, slightly soluble in water, miscible with alcohol.
bp: about 130 °C.

A colourless liquid, slightly soluble in water, miscible with alcohol.
bp: about 261 °C.

Iron salicylate solution. 1046700. 1046800. [91-56-5].
Indoline-2,3-dione. Small, yellowish-red crystals, slightly soluble in water, soluble in hot water and in alcohol, soluble in solutions of alkali hydroxides giving a violet colour becoming yellow on standing.

mp: about 200 °C, with partial sublimation.
**4.1.1. Reagents**

**Isomenthol.** \( C_{10}H_{12}O \) (\( M \), 156.3). 1047000. [23283-97-8]. (+)-Isomenthol: (1S,2R,5R)-2-isopropyl-5-methylcyclohexanol. (-)-Isomenthol: a mixture of equal parts of (1S,2R,5R)- and (1R,2S,5S)-2-isopropyl-5-methylcyclohexanol.

Colourless crystals, practically insoluble in water, very soluble in alcohol.

\[ [\alpha]_D^{20} : (+)-\text{Isomenthol: about} + 24, \text{determined on a 100 g/1 solution in alcohol R}. \]

bp: (+)-Isomenthol: about 218 °C. (-)-Isomenthol: about 218 °C.

mp: (+)-Isomenthol: about 80 °C. (-)-Isomenthol: about 53 °C.

(+)-Isomenthene. \( C_{10}H_{18}O \). (\( M \), 154.2). 1047100. (1R)-cis-p-Menthane-3-one. (1R)-cis-2-Isopropyl-5-methylcyclohexanone.

Contains variable amounts of menthone. A colourless liquid, very slightly soluble in water, soluble in alcohol.

\[ d_20 : 0.904. \]

\[ \beta_20 : 1.453. \]

\[ [\alpha]_D^{20} : \text{about} + 93.2. \]

Isomenthene used in gas chromatography complies with the following additional test.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Peppermint oil (0405) using the test substance as examined to be the test solution.

The area of the principal peak is not less than 80.0 per cent of the total area of the peaks.

**Isopropylamine.** \( C_3H_7N \). (\( M \), 59.1). 1119800. [75-31-0].

Propan-2-amine.

A colourless, highly volatile, flammable liquid.

\[ n_D^20 : \text{about} 1.374. \]

bp: 32 °C to 34 °C.

**Isopropyl iodide.** \( C_3H_7I \). (\( M \), 170.0). 1166600. [75-30-9].

2-Iodopropane.

**Isopropyl myristate.** 1047200. [110-27-0].

See Isopropyl myristate (0725).

**4-Isopropenylphenol.** \( C_9H_{12}O \). (\( M \), 136.2). 1047300. [99-89-8].

**Content:** minimum 98 per cent of \( C_9H_{12}O \).

bp: about 212 °C.

mp: 59 °C to 61 °C.

**Isopulegol.** \( C_{10}H_{16}O \). (\( M \), 154.2). 1139600. [89-79-2].

(-)-Isopulegol. (1R,2S,5R)-2-Isopropenyl-5-methylcyclohexanol.

\[ d_20 : \text{about} 0.911. \]

\[ n_D^20 : \text{about} 1.472. \]

bp: about 91 °C.

Isopulegol used in gas chromatography complies with the following additional test.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Mint oil, partly dementholised (1838).

The content is not less than 99 per cent, calculated by the normalisation procedure.

**Isoquercitrin.** \( C_{21}H_{20}O_{12} \). 1136500. [21637-25-2].

Isoquercitrin. 2-(3,4-Dihydroxyphenyl)-3(β-D-glucofuranosyloxy)-5,7-dihydroxy-4H-1-benzopyran-4-one. 3,3′,4,5,7-Pentahydroxyflavone-3-glucoside.

White or yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

**Kaolin, light.** 1047400. [1332-58-7].

A purified native hydrated aluminium silicate. It contains a suitable dispersing agent.

A light, white or almost white powder free from gritty particles, unctuous to the touch, practically insoluble in water and in mineral acids.

**Coarse particles.** Place 5.0 g in a ground-glass-stoppered cylinder about 160 mm long and 35 mm in diameter and add 60 ml of a 10 g/1 solution of sodium pyrophosphate R. Shake vigorously and allow to stand for 5 min. Using a pipette, remove 50 ml of the liquid from a point about 5 cm below the surface. To the remaining liquid add 50 ml of water R, shake, allow to stand for 5 min and remove 50 ml as before. Repeat the operations until a total of 400 ml has been removed. Transfer the remaining suspension to an evaporating dish. Evaporate to dryness on a water-bath and dry the residue to constant mass at 100 °C to 105 °C. The residue weighs not more than 25 mg (0.5 per cent).

**Fine particles.** Disperse 5.0 g in 250 ml of water R by shaking vigorously for 2 min. Immediately pour into a glass cylinder 50 mm in diameter and, using a pipette, transfer 20 ml to a glass dish, evaporate to dryness on a water-bath and dry to constant mass at 100 °C to 105 °C. Allow the remainder of the suspension to stand at 20 °C for 4 h and, using a pipette with its tip exactly 5 cm below the surface, withdraw a further 20 ml without disturbing the sediment, place in a glass dish, evaporate to dryness on a water-bath and dry to constant mass at 100 °C to 105 °C. The mass of the second residue is not less than 70 per cent of that of the first residue.

**11-Keto-β-boswellic acid.** \( C_{30}H_{46}O_4 \). (\( M \), 470.7). 1167600. [17019-92-0]. 3α-Hydroxy-11-oxours-12-en-24-oic acid. (4β)3α-Hydroxy-11-oxours-12-en-23-oic acid.

White or almost white powder, insoluble in water, soluble in acetone, in anhydrous ethanol and in methanol.

mp: 195 °C to 197 °C.

**11-Keto-β-boswellic acid used in liquid chromatography complies with the following additional test.**

**Assay.** Liquid chromatography (2.2.29) as prescribed in the monograph on Indian frankincense (2310).

Content: minimum 90 per cent, calculated by the normalisation procedure.

**Kieselguhr for chromatography.** 1047500.

A white or yellowish-white, light powder, practically insoluble in water, in dilute acids and in organic solvents.

**Filtration rate.** Use a chromatography column 0.25 m long and 10 mm in internal diameter with a sintered-glass (100) plate and two marks at 0.10 m and 0.20 m above the plate. Place sufficient of the substance to be examined in the column to reach the first mark and fill to the second mark with water R. When the first drops begin to flow from the column, fill to the second mark again with water R and measure the time required for the first 5 ml to flow from the column. The flow rate is not less than 1 ml/min.

**Appearance of the eluate.** The eluate obtained in the test for filtration rate is colourless (Method I, 2.2.2).
Acidity or alkalinity. To 1.00 g add 10 ml of water R, shake vigorously and allow to stand for 5 min. Filter the suspension on a filter previously washed with hot water R until the washings are neutral. To 2.0 ml of the filtrate add 0.05 ml of methyl red solution R; the solution is yellow. To 2.0 ml of the filtrate add 0.05 ml of phenolphthalein solution R1; the solution is at most slightly pink.

Water-soluble substances. Place 10.0 g in a chromatography column 0.25 m long and 10 mm in internal diameter and elute with water R. Collect the first 20 ml of eluate, evaporate to dryness and dry the residue at 100 °C to 105 °C. The residue weighs not more than 10 mg.

Iron to dryness and dry the residue at 100 °C to 105 °C. The eluate with column 0.25 m long and 10 mm in internal diameter and water R, shake vigorously, allow to stand for 5 min and filter. 1.0 ml of the filtrate complies with the limit test for iron (200 ppm).

Loss on ignition: maximum 0.5 per cent. During heating to red heat (600 ± 50 °C) the substance does not become brown or black.

Kieselguhr G. 1047600.
Consists of kieselguhr treated with hydrochloric acid and calcined, to which is added about 15 per cent of calcium sulphate hemihydrate.

A fine greyish-white powder; the grey colour becomes more pronounced on triturating with water. The average particle size is 10 µm to 40 µm.

Calcium sulphate content. Determine by the method prescribed for silica gel G R.

pH (2.2.3). Shake 1 g with 10 ml of carbon dioxide-free water R for 5 min. The pH of the suspension is 7 to 8.

Chromatographic separation. Examine by thin-layer chromatography (2.2.27). Prepare plates using a slurry of the kieselguhr G with a 2.7 g/l solution of sodium acetate R. Apply 5 µl of a solution containing 0.1 g/l of lactose, sucrose, glucose and fructose in pyridine R2. Develop over a path of 14 cm using a mixture of 12 volumes of water R, 23 volumes of 2-propanol R and 65 volumes of ethyl acetate R. The migration time of the solvent is about 40 min. Dry, spray onto the plate about 10 ml of anisaldehyde solution R and heat for 5 min to 10 min at 100 °C to 105 °C. The chromatogram shows four well-defined spots without tailing and well separated from each other.

Lactic acid. 1047800. [50-21-5].
See Lactic acid (0458).

Lactic reagent. 1047801.

Solution A. To 60 ml of lactic acid R add 45 ml of previously filtered lactic acid R saturated without heating with Sudan red G R; as lactic acid saturates slowly without heating, an excess of colorant is always necessary. Solution B. Prepare 10 ml of a saturated solution of aniline R. Filter.

Solution C. Dissolve 75 mg of potassium iodide R in water and dilute to 70 ml with the same solvent. Add 10 ml of alcohol R and 0.1 g of iodine R. Shake.

Mix solutions A and B. Add solution C.


Freely soluble in pyridine and in dioxane.

Lanthanum chloride heptahydrate. LaCl₃·7H₂O. (M, 371.4). 1167200. White or almost white powder or colourless crystals, freely soluble in water.

Lanthanum nitrate. La(NO₃)₃·6H₂O. (M, 433.0). 1048000. White or almost white powder or colourless crystals, freely soluble in water.

Storage: in an airtight container.
**Lanthanum nitrate solution.** 1048001.
A 50 g/1 solution.

**Lanthanum trioxide.** La₂O₃. (M, 325.8). 1114000. [1312-81-8].
An almost white, amorphous powder, practically insoluble in water R. It dissolves in dilute solutions of mineral acids and absorbs atmospheric carbon dioxide.
Calcium: maximum 5 ppm.

**Lanthanum chloride solution.** 1114001.
To 58.65 g of lanthanum trioxide R slowly add 100 ml of hydrochloric acid R. Heat to boiling. Allow to cool and dilute to 1000.0 ml with water R.

**Lauric acid.** C₁₂H₂₄O₂. (M, 200.3). 1143100. [143-07-7].
Dodecanoic acid.
White or almost white, crystalline powder, practically insoluble in water, freely soluble in alcohol.
mp: about 44 °C.
Lauric acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.
Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848). The content of lauric acid is not less than 98 per cent calculated by the normalisation procedure.

**Lauryl alcohol.** C₁₂H₂₅O. (M, 186.3). 11199000. [112-53-8].
1-Dodecanol.
d²₀: about 0.820.
mp: 24 °C to 27 °C.

**Lavandulol.** C₁₀H₁₆O₃. (M, 154.2). 11141000. [498-16-8].
(R)-5-Methyl-2-(1-methylethenyl)-4-hexen-1-ol.
An oily liquid with a characteristic odour.
Lavandulol used in gas chromatography complies with the following additional test.
Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Lavender oil (1338). The area of the principal peak is not less than 90.0 per cent of the area of all the peaks in the chromatogram obtained.

**Lavandulyl acetate.** C₁₂H₂₆O₄Pb₂. (M, 295.2). 11142000. [50373-59-6]. 2-(1-Methylethyl)-4-hexen-1-yl acetate.
A colourless liquid with a characteristic odour.
d²₀: about 0.911.
ν₂₀: about 1.454.
b₁₁: 106 °C to 107 °C.
Lavandulyl acetate used in gas chromatography complies with the following additional test.
Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Lavender oil (1338). The area of the principal peak is not less than 93.0 per cent of the area of all the peaks in the chromatogram obtained.

**Lead acetate.** C₁₂H₂₆O₄Pb₃H₂O. (M, 379.3). 10481000. [6090-56-4]. Lead diacetate.
A white or almost white, crystalline powder or colourless crystals, freely soluble in water, soluble in alcohol.

**Lead acetate cotton.** 1048101.
Immerse absorbent cotton in a mixture of 1 volume of dilute acetic acid R and 10 volumes of lead acetate solution R. Drain off the excess of liquid, without squeezing the cotton, by placing it on several layers of filter paper. Allow to dry in air.
Storage: in an airtight container.

**Lead acetate paper.** 1048102.
Immerse filter paper weighing about 80 g/m² in a mixture of 1 volume of dilute acetic acid R and 10 volumes of lead acetate solution R. After drying, cut the paper into strips 15 mm by 40 mm.

**Lead acetate solution.** 1048103.
A 95 g/1 solution in carbon dioxide-free water R.

**Lead dioxide.** PbO₂. (M, 239.2). 10482000. [1309-60-0].
A dark brown powder, evolving oxygen when heated, practically insoluble in water, soluble in hydrochloric acid with evolution of chlorine, soluble in dilute nitric acid in the presence of hydrogen peroxide, oxalic acid or other reducing agents, soluble in hot, concentrated alkali hydroxide solutions.

**Lead nitrate.** Pb(NO₃)₂. (M, 331.2). 10483000. [10099-74-8].
Lead dinitrate.
A white or almost white, crystalline powder or colourless crystals, freely soluble in water.

**Lead nitrate solution.** 1048301.
A 33 g/1 solution.

**Lead subacetate solution.** 10484000. [1335-32-6]. Basic lead acetate solution.
Content: 16.7 per cent m/m to 17.4 per cent m/m of Pb (A, 207.2) in a form corresponding approximately to the formula C₈H₈O₃Pb₃.
Dissolve 40.0 g of lead acetate R in 90 ml of carbon dioxide-free water R. Adjust the pH to 7.5 with strong sodium hydroxide solution R. Centrifuge and use the clear colourless supernatant solution.
The solution remains clear when stored in a well-closed container.

**Leiocarposide.** C₃₀H₃₆O₁₈. (M, 614.5). 11502000. [71953-77-0]. 2-D-[β-D-Glucopyranosyloxy]-3-[β-D-glucopyranosyl]oxy-6-hydroxy-2-methoxybenzozate.
Dissolve 0.1 g of leiocarposide R in 10 ml of carbon dioxide-free water R. Adjust the pH to 7.5 with strong sodium hydroxide solution R. Centrifuge and use the clear colourless supernatant solution.
The solution remains clear when stored in a well-closed container.

**Lemon oil.** 1101700.
See Lemon oil (0620).

**Leucine.** 10485000. [61-90-5].
See Leucine (0771).

**Levodopa.** 1170000. [59-92-7].
See Levodopa (0038).

A colourless liquid, practically insoluble in water, soluble in ethanol (96 per cent).
d²₀: about 0.84.
ν₂₀: 1.471 to 1.474.
Limonene used in gas chromatography complies with the following additional test.

**Assay.** Gas chromatography (2.2.28) as prescribed in the monograph on Peppermint oil (0405).

**Test solution.** The substance to be examined.

The area of the principal peak is not less than 99.0 per cent of the total area of the peaks.

**Linalol.** C_{10}H_{16}O. (M, 154.2). 1048700. [78-70-6]. (RS)-3,7-Dimethylocta-1,6-dien-3-ol.

Mixture of two stereoisomers (licareol and coriandrol).

Liquid, practically insoluble in water.

\[ \delta^20 \text{: about } 0.860. \]

\[ \eta^D \text{: about } 1.462. \]

bp: about 200 °C.

Linalol used in gas chromatography complies with the following test.

**Assay.** Examine by gas chromatography (2.2.28) under the conditions described in the monograph on Anise oil (0804) using the substance to be examined as the test solution.

The area of the principal peak is not less than 98.0 per cent of the total area of the peaks.

**Linalyl acetate.** C_{15}H_{22}O_2. (M, 196.3). 1107200. [115-95-7]. (RS)-1,5-Dimethyl-1-vinylhex-4-enyl acetate.

A colourless or slightly yellow liquid with a strong odour of bergamot and lavender.

\[ \delta^20 \text{: } 0.895 \text{ to } 0.912. \]

\[ \eta^D \text{: } 1.448 \text{ to } 1.451. \]

bp: about 215 °C.

Linalyl acetate used in gas chromatography complies with the following additional test.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Bitter-orange-flower oil (1175) using the substance to be examined as the test solution.

The area of the principal peak is not less than 95.0 per cent of the total area of the peaks.

**Lindane.** C_{16}H_{18}Cl_6. (M, 290.8). 1128900. [58-89-9]. γ-Hexachlorocyclohexane.

See Lindane (0772).

For the monograph Wool fat (0134), a suitable certified reference solution (10 ng/μl) in hexane (may be used).

**Linoleic acid.** C_{18}H_{32}O_2. (M, 280.5). 1143200. [60-33-3]. (9Z,12Z)-Octadeca-9,12-dienoic acid.

Colourless, oily liquid.

\[ \delta^20 \text{: about } 0.903. \]

\[ \eta^3 \text{: about } 1.470. \]

Linoleic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848).

The content of linoleic acid is not less than 98 per cent, calculated by the normalisation procedure.

**Linolenic acid.** C_{18}H_{30}O_2. (M, 278.4). 1143300. [463-40-1]. (9Z,12Z,15Z)-Octadeca-9,12,15-trienoic acid.

Colourless liquid, practically insoluble in water, soluble in organic solvents.

\[ \delta^20 \text{: about } 0.915. \]

\[ \eta^1 \text{: about } 1.480. \]

Linolenic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848).

The content of linolenic acid is not less than 98 per cent, calculated by the normalisation procedure.

**Linolenyl alcohol.** C_{18}H_{34}O. (M, 264.4). 1155400. [506-43-4]. (9Z,12Z)-Octadeca-9,12-dien-1-ol.

Relative density: 0.830.

Content: minimum 85 per cent of C_{18}H_{34}O.

**Liquid scintillation cocktail.** 1167300.

Commercially available solution for the determination of radioactivity by liquid scintillation counting. It contains one or more fluorescent agents and mostly one or more emulsifying agents in a suitable organic solvent or mixture of organic solvents.

**Lithium.** Li. (A, 6.94). 1048800. [7439-93-2].

A soft metal whose freshly cut surface is silvery-grey. It rapidly tarnishes in contact with air. It reacts violently with water, yielding hydrogen and giving a solution of lithium hydroxide; soluble in methanol, yielding hydrogen and a solution of lithium methoxide; practically insoluble in light petroleum.

**Storage:** under light petroleum or liquid paraffin.

**Lithium carbonate.** Li_2CO_3. (M, 73.9). 1048900. [554-13-2]. Dilithium carbonate.

A white or almost white, light powder, sparingly soluble in water, very slightly soluble in alcohol. A saturated solution at 20 °C contains about 13 g/1 of Li_2CO_3.

**Lithium chloride.** LiCl. (M, 42.39). 1049000. [7447-41-8].

Crystalline powder or granules or cubic crystals, deliquescent, freely soluble in water, soluble in acetone and in alcohol. Aqueous solutions are neutral or slightly alkaline.

**Storage:** in an airtight container.

**Lithium hydroxide.** LiOH.H_2O. (M, 41.96). 1049100. [1310-66-3]. Lithium hydroxide monohydrate.

A white or almost white, granular powder, strongly alkaline, it rapidly absorbs water and carbon dioxide, soluble in water, sparingly soluble in alcohol.

**Storage:** in an airtight container.

**Lithium metaborate, anhydrous.** LiBO_2. (M, 49.75). 1120000. [13453-69-5].

**Lithium sulphate.** Li_2SO_4.H_2O. (M, 128.0). 1049200. [10102-25-7]. Dilithium sulphate monohydrate.

Colourless crystals, freely soluble in water, practically insoluble in alcohol.

**Litmus.** 1049300. [1393-92-6].

Schultz No. 1386.

Indigo-blue fragments prepared from various species of Rocella, Lecanora or other lichens, soluble in water, practically insoluble in alcohol.

**Colour change:** pH 5 (red) to pH 8 (blue).
**Litmus paper, blue.** 1049301.
Boil 10 parts of coarsely powdered *litmus* R for 1 h with 100 parts of *alcohol R*. Decant the alcohol and add to the residue a mixture of 45 parts of *alcohol R* and 55 parts of *water R*. After 2 days decant the clear liquid. Impregnate strips of filter paper with the solution and allow to dry. 
**Test for sensitivity.** Immers a strip measuring 10 mm by 60 mm in a mixture of 10 ml of 0.02 M *hydrochloric acid* and 90 ml of *water R*. On shaking the paper turns red within 45 s.

**Litmus paper, red.** 1049302.
To the blue litmus extract, add *dilute hydrochloric acid R* dropwise until the blue colour becomes red. Impregnate strips of filter paper with the solution and allow to dry. 
**Test for sensitivity.** Immers a strip measuring 10 mm by 60 mm in a mixture of 10 ml of 0.02 M *sodium hydroxide* and 90 ml of *water R*. On shaking the paper turns blue within 45 s.

**Longifolene.** C15H24. (mp: 220 °C to 221 °C. 4-carboxylate. with alcohol. Oily, colourless liquid, practically insoluble in water, miscible with benzene, acetonitrile, methanol R, dextrorotary with lauryl alcohol being 23.)

**Loganin.** C15H14O8. (M, 290.4). 1127500. [18524-94-2]. Methyl (1S,3aR,7aR,11aR)-1-b-D-glucopyranosyl)-6-hydroxy-7-methyl-1,4a,5,6,7,7a-hexahydrocyclopenta[c]pyran-4-carboxylate.

mp: 220 °C to 221 °C.

**Longifolene.** C15H24. (M, 204.4). 1150300. [475-20-7]. (1S,3aR,7aR,11aR)-1-b-D-glucopyranosyl)-6-hydroxy-7-methyl-1,4a,5,6,7,7a-hexahydrocyclopenta[c]pyran-4-carboxylate.

Oily, colourless liquid, practically insoluble in water, miscible with alcohol.

\[d_1^20: 0.9319.\]

\[\eta_20: 1.5050.\]

\[\beta_20: + 42.7.\]

bp: 254 °C to 256 °C.

**Longifolene used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on *Turpentine oil, Pinus pinaster type* (1627).

The content is not less than 98.0 per cent, calculated by the normalisation procedure.

**Low-vapour-pressure hydrocarbons (type L).** 1049400.
Uncrystallised mass, soluble in benzene and in toluene.

**Lumiflavine.** C18H14N2O4. (M, 256.3). 1141000. [108856-8]. 7,8,10-Trimethylbenzo[4]teridine-2,4(3H,10H)-dione. Yellow powder or orange crystals, very slightly soluble in water, freely soluble in methylene chloride.

**Luteolin-7-glucoside.** C21H20O11. (M, 448.4). 1163400. [5373-11-5]. 2.2.25

\[2(3,4-Dihydroxyphenyl)-7-(\beta-D-glucopyranosyl)3-hydroxy-AP1-benzopyran-4-one.\]

Yellow powder.

Absorbance (2.2.25). A solution in methanol R shows absorption maxima at 255 nm, 267 nm, 290 nm and 350 nm. 

mp: about 247 °C.

**Macrogol 23 lauryl ether.** 1129000.
Complies with the monograph *Macrogol lauryl ether* (1124), the nominal value for the amount of ethylene oxide reacted with lauryl alcohol being 23.


A clear, colourless or almost colourless viscous liquid, very soluble in acetone and in ethanol, practically insoluble in fatty oils.

\[d_20^2: \text{about 1.127.}\]

\[\eta_2: \text{about 1.450.}\]

**Macrogol 200 R1.** 1099201.
Introduce 500 ml of *macrogol 200 R* into a 1000 ml round bottom flask. Using a rotation evaporator remove any volatile components applying for 6 h a temperature of 60 °C and a vacuum with a pressure of 1.5 kPa to 2.5 kPa.

**Macrogol 300.** 1067100. [25322-68-3]. Polyethylene glycol 300.
See Macrogols (1444).

**Macrogol 400.** 1067200. [25322-68-3]. Polyethylene glycol 400.
See Macrogols (1444).

**Macrogol 1000.** 1067300. [25322-68-3]. Polyethylene glycol 1000.
See Macrogols (1444).

**Macrogol 1500.** 1067400. [25322-68-3]. Polyethylene glycol 1500.
See Macrogols (1444).

**Macrogol 20 000.** 1067600. Polyethylene glycol 20 000.
See Macrogols (1444).

**Macrogol 20 000 2-nitroterephthalate.** 1067601.
Polyethylene glycol 20 000 2-nitroterephthalate. 

**Macrogol 20 000 R modified by treating with 2-nitroterephthalic acid.**

A hard, white or almost white, waxy solid, soluble in acetone.

**Magnesium.** Mg. (A, 24.30). 1049500. [7439-95-4].
Silver-white ribbon, turnings or wire, or a grey powder.

**Magnesium acetate.** C4H6MgO4,4H2O. (M, 166). 1049600. [16674-78-5]. Magnesium diacetate tetrahydrate.

Colourless crystals, deliquescent, freely soluble in water and in alcohol.

**Storage:** in an airtight container.

**Magnesium chloride.** 1049700. [7791-18-6].
See Magnesium chloride hexahydrate (0402).

**Magnesium nitrate.** Mg(NO3)2.6H2O. (M, 214.5). 1049800. [13446-18-9]. Magnesium nitrate hexahydrate.

Colourless, clear crystals, deliquescent, very soluble in water, freely soluble in alcohol.

**Storage:** in an airtight container.

**Magnesium nitrate solution.** 1049801.
Dissolve 17.3 g of *magnesium nitrate* R in 5 ml of *water R* warming gently and add 80 ml of *alcohol R*. Cool and dilute to 100.0 ml with the same solvent.

**Magnesium nitrate solution R1.** 1049802.
Dissolve 20 g of *magnesium nitrate* R (Mg(NO3)2.6H2O) in *deionised distilled water* R and dilute to 100 ml with the same solvent. Immediately before use, dilute 10 ml to 100 ml with *deionised distilled water R*. A volume of 5 μl will provide 0.06 mg of Mg (NO3)2.
Magnesium oxide. 1049900. [1309-48-4].
See Light magnesium oxide (0040).

Magnesium oxide R1. 1049901.
Complies with the requirements prescribed for magnesium oxide R with the following modifications.
Arsenic (2.4.2). Dissolve 0.5 g in a mixture of 5 ml of water R and 5 ml of hydrochloric acid R1. The solution complies with limit test A for arsenic (2 ppm).

Heavy metals (2.4.8). Dissolve 1.0 g in a mixture of 3 ml of water R and 7 ml of hydrochloric acid R1. Add 0.05 ml of phenolphthalein solution R and concentrated ammonia R until a pink colour is obtained. Neutralise the excess of ammonia by the addition of glacial acetic acid R. Add 0.5 ml in excess and dilute to 20 ml with water R. Filter, if necessary. 12 ml of the solution complies with limit test A for heavy metals (10 ppm).

Preparation of the standard using a mixture of 5 ml of lead standard solution (1 ppm Pb) R and 5 ml of water R.
Iron (2.4.9). Dissolve 0.2 g in 6 ml of dilute hydrochloric acid R and dilute to 10 ml with water R. The solution complies with the limit test for iron (50 ppm).

Magnesium oxide, heavy. 1050000. [1309-48-4].
See Heavy magnesium oxide (0041).

Magnesium silicate for pesticide residue analysis. 1129100. [1343-88-0].
Magnesium silicate for chromatography (60-100 mesh).

Magnesium sulphate. 1050200. [10034-99-8].
See Magnesium sulphate heptahydrate (0044).

Maize oil. 1050400.
See Maize oil, refined (1342).

Schultz No. 754.
Colour Index No. 42000.

Green crystals with a metallic lustre, very soluble in water, slightly soluble in alcohol and in methanol.

A 0.01 g/1 solution in alcohol R shows an absorption maximum (2.2.25) at 617 nm.

Malachite green solution. 1050501.
A 5 g/1 solution in anhydrous acetic acid R.

Malathion. C11H12O4PS2 (M, 330.3). 1129200. [121-75-5].
bp: about 156 °C.
A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Maleic acid. 1050600. [110-16-7].
See Maleic acid (0365).

Maleic anhydride. C4H2O3 (M, 98.1). 1050700. [108-31-6].
Butenedioic anhydride. 2,5-Furandione.

White or almost white crystals, soluble in water forming maleic acid, very soluble in acetone and in ethyl acetate, freely soluble in toluene, soluble in alcohol with ester formation, very slightly soluble in light petroleum.

mp.: about 52 °C.

Any residue insoluble in toluene does not exceed 5 per cent (maleic acid).

Maleic anhydride solution. 1050701.
Dissolve 5 g of maleic anhydride R in toluene R and dilute to 100 ml with the same solvent. Use within one month. If the solution becomes turbid, filter.

Maltitol. 1136800. [585-88-6].
See Maltitol (1235).

Manganese sulphate. MnSO4·H2O. (M, 169.0). 1050900. [10034-96-5].
Manganese sulphate monohydrate.
Pale-pink, crystalline powder or crystals, freely soluble in water, practically insoluble in alcohol.

Loss on ignition: 10.0 per cent to 12.0 per cent, determined on 1.000 g at 500 ± 50 °C.

Mannitol. 1051000. [69-65-8].
See Mannitol (0559).

D(-)-Mannose.

white or almost white, crystalline powder or small crystals, very soluble in water, slightly soluble in ethanol.

$[\alpha]_D^{20}: + 13.7 + 14.7$, determined on a 200 g/1 solution in water R containing about 0.05 per cent of NH3.

mp: about 132 °C, with decomposition.

(2a,5a,6a,7,8a,9,10b,11b,12b,13b,14b,15b,16b,17b,18b,19b,20b,21b,22b,23b,24b,25b-hexacosahydro-4H,7H-estrane). (4R)-4,5,6-Trimethyl-6-oxo-2,3,4,5-tetrahydrofuran-2-carboxylic acid.

Colourless, microcrystalline powder.

Marrubiin used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (2.2.29) as prescribed in the monograph on White horehound (1835).

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Meclozine hydrochloride. 1051200. [1104-22-9].
See Meclozine hydrochloride (0622).

1,3,5-Triazine-2,4,6-triamine.
A white or almost white, amorphous powder, very slightly soluble in water and in alcohol.

Menadione. 1051400. [58-27-5].
See Menadione (0507).

Menthofuran. C10H14O. (M, 150.2). 1051500. [17957-94-7].
3,9-Epoxy-3,9-methano-3,8-diene.
3,6-Dimethyl-4,5,6,7-tetrahydro-benzofuran.
A slightly bluish liquid, very slightly soluble in water, soluble in alcohol.

$\delta^T_0$: about 0.965.

$\nu_0$: about 1.480.

$\nu_1^{20}$: about + 93.

bp: 196 °C.

Menthofuran used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Peppermint oil (0405) using the substance to be examined as the test solution.

The area of the principal peak is not less than 97.0 per cent of the total area of the peaks.

General Notices (1) apply to all monographs and other texts
4.1.1. Reagents

Menthol. 1051600. [2216-51-5]. See Levomenthol (0619) and Racemic menthol (0623).

Menthol used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the Related substances test included in the monograph on Racemic menthol (0623).

The area of the principal peak is not less than 98.0 per cent of the total area of the peaks, disregarding any peak due to the solvent.

Menthone. C_{10}H_{18}O. (–)-Menthone.

Contains variable amounts of isomenthone.

White or almost white crystals, freely soluble in water, soluble in alcohol.

A colourless liquid, very slightly soluble in water, miscible with the solvent.

2-Isopropyl-5-methylcyclohexyl acetate. [2623-23-6]. 2-Isopropyl-5-methylcyclohexanol.

Menthone used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Peppermint oil (0405) using the substance to be examined as the test solution.

The area of the principal peak is not less than 90.0 per cent of the total area of the peaks.

Menthyl acetate. C_{12}H_{22}O_{2}. (–)-Menthyl acetate.

Contains variable amounts of isomenthyl acetate.

A colourless liquid, slightly soluble in water, miscible with alcohol.

Mercuric acetate. HgC_{2}H_{4}O. (M, 198.3). 1051800.


White or faintly yellow crystals or a crystalline powder, slightly soluble in water, soluble in alcohol.

Mercuric bromide paper. 1052101.

In a rectangular dish place a 50 g/l solution of mercuric bromide R in ethanol R and immerse in it pieces of white filter paper weighing 80 g per square metre (speed of filtration = filtration time expressed in seconds for 100 ml of water at 20 °C with a filter surface of 10 cm² and constant pressure of 6.7 kPa; 40 s to 60 s), each measuring 1.5 cm by 20 cm and folded in two. Allow the excess liquid to drain and allow the paper to dry, protected from light, suspended over a non-metallic thread. Discard 1 cm from each end of each strip and cut the remainder into 1.5 cm squares or discs of 1.5 cm diameter.

Storage. in a glass-stoppered container wrapped with black paper.

Mercuric chloride. 1052200. [7487-94-7].

See Mercuric chloride (0129).

Mercuric chloride solution. 1052201.

A 54 g/l solution.

Mercuric iodide. HgI_{2}. (M, 454.4). 1052300. [7774-29-0].

Mercury di-iodide.

A dense, scarlet, crystalline powder, slightly soluble in water, sparingly soluble in acetone and in alcohol, soluble in an excess of potassium iodide solution R.

Storage. protected from light.

Mercuric nitrate. Hg(NO_{3})_{2}.H_{2}O. (M, 342.6). 1052400. [7783-34-8]. Mercuric nitrate monohydrate.

Colourless or slightly coloured crystals, hygroscopic, soluble in water in the presence of a small quantity of nitric acid.

Storage. in an airtight container, protected from light.


Yellow mercuric oxide. Mercury oxide.

A yellow to orange-yellow powder, practically insoluble in water and in alcohol.

Storage. protected from light.

Mercuric sulphate solution. 1052600. [7783-35-9].

Dissolve 1 g of mercuric oxide R in a mixture of 20 ml of water R and 4 ml of sulphuric acid R.

Mercuric thiocyanate. Hg(SCN)_{2}. (M, 316.7). 1052700. [592-85-8].

White or almost white crystals, freely soluble in water, soluble in solutions of sodium chloride.

Mercuric thiocyanate solution. 1052701.

Dissolve 0.3 g of mercuric thiocyanate R in ethanol R and dilute to 100 ml with the same solvent.

Storage. use within 1 week.

Mercury. Hg. (A, 200.6). 1052800. [7439-97-6].

A silver-white liquid, breaking into spherical globules which do not leave a metallic trace when rubbed on paper.

bp: about 357 °C.

| Mercuric acetate solution. 1052001. |
| Dissolve 3.19 g of mercuric acetate R in anhydrous acetic acid R and dilute to 100 ml with the same acid. If necessary, neutralise the solution with 0.1 M perchloric acid using 0.05 ml of crystal violet solution R as indicator. |
| bp: about 135 °C. |
Mercuric nitric acid solution. 1052801.
Carefully dissolve 3 ml of mercuric R in 27 ml of fuming nitric acid R. Dilute the solution with an equal volume of water R.
Storage: protected from light; use within 2 months.

Mesityl oxide. C₉H₈O. (M, 98.1). 1120100. [141-79-7].
4-Methylpent-3-en-2-one.
Colourless, oily liquid, solidifying at about 20 °C, miscible with water, slightly soluble in toluene, practically insoluble in hexane.
$\eta_20^\circ$: about 0.37.
$\eta_25^\circ$: about 1.48.

Metaphosphoric acid. H₃PO₃. Dissolve 35.0 g in 50 ml of water. A brownish-yellow powder, soluble in water and in alcohol.

Sodium 3-[4-(phenylamino)phenylazo]benzenesulphonate.
A clear, colourless liquid, solidifying at about 16 °C.
bp: about 346 °C.

Metanil yellow solution. 1052901.
A 1 g / l solution in methanol R.
Test for sensitivity. To 50 ml of anhydrous acetic acid R add 0.1 ml of the metanil yellow solution. Add 0.05 ml of 0.1 M perchloric acid; the colour changes from pinkish-red to violet.

Metaphosphoric acid. (HPO₃)₂. 1053000. [37267-86-0].
Glassy lumps or sticks containing a proportion of sodium metaphosphate, hygroscopic, very soluble in water.

Methacrylic acid. C₅H₈O₂. (M, 86.1). 1101800. [79-41-4].
2-Methylprop-2-enoic acid.
A colourless liquid.
$\eta_20^\circ$: about 1.431.
bp: about 160 °C.
mp: about 16 °C.

Methane. CH₄. (M, 16). 1166300. [74-82-8].
Content: minimum 99.0 per cent V/V of CH₄.

Methanesulphonic acid. CH₃SO₃H. (M, 96.1). 1053100. [75-75-2].
A clear, colourless liquid, solidifying at about 20 °C, miscible with water, slightly soluble in toluene, practically insoluble in hexane.
$\eta_20^\circ$: about 1.48.
$\eta_25^\circ$: about 1.430.

Methanol. CH₃O. (M, 32.04). 1053200. [67-56-1].
A clear, colourless, flammable liquid, miscible with water and with alcohol.
$\eta_20^\circ$: 0.791 to 0.793.
bp: 64 °C to 65 °C.

Methanol R1. 1053201.
Complies with the requirements prescribed for methanol R and the following additional requirement.

**Minimum transmittance** (2.2.25). The absorbance at 225 nm using water R as the compensation liquid is not more than 0.17.

Methanol R2. 1053202.
Complies with the requirements prescribed for methanol R and the following additional requirements.
Content: minimum 99.8 per cent of CH₃O (M, 32.04).

Methanol, hydrochloric. 1053203.
Dilute 1.0 ml of hydrochloric acid R1 to 100.0 ml with methanol R.

Methanol, aldehyde-free. 1053300.
Dissolve 25 g of iodine R in 1 litre of methanol R and pour the solution, with constant stirring, into 400 ml of 1 M sodium hydroxide. Add 150 ml of water R and allow to stand for 16h. Filter. Boil under a reflux condenser until the odour of iodoform disappears. Distil the solution by fractional distillation.
Content: maximum 0.001 per cent of aldehydes and ketones.

Methanol, anhydrous. 1053400. [67-56-1].
 Treat 1000 ml of methanol R with 5 g of magnesium R. If necessary initiate the reaction by adding 0.1 ml of mercuric chloride solution R. When the evolution of gas has ceased, distil the liquid and collect the distillate in a dry container protected from moisture.
Water (2.5.12): maximum 0.3 g / l.

DL-Methionine. 1129400. [59-51-8].
See DL-Methionine (0624).

L-Methionine. 1053500. [63-68-3].
See Methionine (1027).

(RS)-Methotrexate. 1120200. [60388-6]. (RS)-2-[4-[(2,4-diaminopteridin-6-yl)methyl][methylamino]benzoylamino]pentanedioic acid.
Content: minimum 96.0 per cent of C₂₀H₂₂N₈O₅.
mp: about 195 °C.

Methoxychlor. C₁₆H₁₅Cl₃O₂. (M, 345.7). 1129300. [72-43-5].
1,1-(2,2,2-Trichloroethylidene)-bis(4-methoxybenzene).
Practically insoluble in water, freely soluble in most organic solvents.
bp: about 346 °C.
mp: 78 °C to 86 °C. A suitable certified reference solution (10 ng / µl in iso-octane) may be used.
**4.1.1. Reagents**

**trans-2-Methoxycinnamaldehyde.** \( \text{C}_9\text{H}_8\text{O}_2 \) (M, 162.2). 1129500. [60125-24-8].

mp: 44 °C to 46 °C.

*trans-2-Methoxycinnamaldehyde used in gas chromatography complies with the following additional test.*

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on *Cassia oil* (1496).

The content is not less than 96.0 per cent, calculated by the normalisation procedure.

**1-(6-Methoxynaphthalen-2-yl)ethanol.** \( \text{C}_{10}\text{H}_{13}\text{NO} \) (M, 166.2). 1053600. [7021-09-2].

mp: about 70 °C.

Sparingly soluble in water, freely soluble in alcohol.

**3-Methoxy-L-tyrosine.** \( \text{C}_9\text{H}_{11}\text{NO}_2 \) (M, 202.3). 1159600. [77301-42-9].

Off-white or yellow powder.

mp: about 113 °C.

**Methoxyphenylacetic acid.** \( \text{C}_9\text{H}_9\text{O}_3 \) (M, 166.2).

A white, crystalline powder or white or almost white crystals, sparingly soluble in water, freely soluble in alcohol.

mp: about 70 °C.

**Methoxyphenylacetic reagent.** 1053601.

Dissolve 2.7 g of methoxyphenylacetic acid R in 6 ml of tetramethylammonium hydroxide solution R and add 20 ml of ethanol R.

**Storage:** in a polyethylene container.

**3-Methoxy-L-tyrosine.** \( \text{C}_9\text{H}_{11}\text{NO}_2 \) (M, 202.3). 1159600. [77301-42-9].

Off-white or yellow powder.

**Methyl acetate.** \( \text{C}_3\text{H}_6\text{O}_2 \) (M, 74.1). 1053700. [79-20-9].

A clear, colourless liquid, soluble in water, miscible with alcohol.

\( \alpha \)-Methylbenzyl isocyanate.

**Methyl anthranilate.** \( \text{C}_8\text{H}_9\text{NO}_2 \) (M, 151.2). 1107300. [134-20-3]. Methyl 2-aminobenzoate.

Colourless crystals or a colourless or yellowish liquid, soluble in water, freely soluble in alcohol.

bp: 134 °C to 136 °C.

mp: 24 °C to 25 °C.

**Methyl anthranilate used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on *Bitter-orange-flower oil* (1175), using the substance to be examined as the test solution. The area of the principal peak is not less than 95.0 per cent of the total area of the peaks.

**Methyl arachidate.** \( \text{C}_{19}\text{H}_{38} \) (M, 326.6). 1053900. [1120-28-1]. Methyl eicosanoate.

**Content:** minimum 98.0 per cent of \( \text{C}_{21}\text{H}_{42} \), determined by gas chromatography (2.4.22).

A white or yellow, crystalline mass, soluble in alcohol and in light petroleum.

mp: about 46 °C.

**Methyl behenate.** \( \text{C}_{18}\text{H}_{36} \) (M, 354.6). 1107500. [929-77-1]. Methyl docosanoate.

mp: 54 °C to 55 °C.

**Methyl benzoate.** \( \text{C}_8\text{H}_8\text{O}_2 \) (M, 122.2).

A colourless, almost white crystal, slightly soluble in water, freely soluble in alcohol.

bp: about 184 °C.

**Methyl benzoate reagent.** 1164500. [93-58-3]. Benzoic acid, methyl ester.

Colourless liquid.

bp: about 200 °C.

**Methyl benzenesulphonate.** \( \text{C}_7\text{H}_8\text{O}_3 \) (M, 147.2).

Methyl benzenesulphonate.

Content: minimum 99.0 per cent.

Suitability for determination of aldehydes. To 2 ml of aldehyde-free methyl R add 50 µl of a 1 g/l solution of propionaldehyde R in aldehyde-free methanol R and 5 ml of a 4 g/l solution of methylbenzothiazolone hydrazone hydrochloride. Mix. Allow to stand for 30 min. Prepare a blank omitting the propionaldehyde solution. Add 25.0 ml of a 2 g/l solution of ferric chloride R to the test solution and to the blank, dilute to 100.0 ml with acetone R and mix. The absorbance (2.2.25) of the test solution, measured at 660 nm using the blank as compensation liquid, is not less than 0.62.

**Methyl benzenesulphonate hydrozone hydrochloride.** \( \text{C}_7\text{H}_8\text{ClN}_3\text{S} \) (M, 233.7). 1053300. [38894-11-0].

3-Methylbenzothiazol-2(3H)-one hydrazone hydrochloride monohydrate.

An almost white or yellowish, crystalline powder.

mp: about 270 °C.

**Methyl benzyl isocyanate.** \( \text{C}_8\text{H}_9\text{ClN}_3\text{O} \) (M, 172.2). 1159800. [80-18-2].

A clear, colourless liquid.

bp: about 184 °C.

**Methyl benzoate.** \( \text{C}_8\text{H}_8\text{O}_2 \) (M, 122.2).

A colourless, almost white crystal, slightly soluble in water, freely soluble in alcohol.

bp: about 184 °C.

**Methyl benzyl isocyanate.** \( \text{C}_8\text{H}_9\text{ClN}_3\text{O} \) (M, 172.2). 1159800. [80-18-2].

A clear, colourless liquid.

bp: about 184 °C.

**Methyl benzoate.** \( \text{C}_8\text{H}_8\text{O}_2 \) (M, 122.2).

A colourless, almost white crystal, slightly soluble in water, freely soluble in alcohol.

bp: about 184 °C.
2-Methylbutane. \( \text{C}_3\text{H}_8 \) (\( M \), 72.2). 1099500. [78-78-4].
Isopentane.

**Content:** minimum 99.5 per cent of \( \text{C}_3\text{H}_8 \).
A very flammable colourless liquid.

d\(^{20} \): about 0.621.
\( \rho_{20} \): about 1.354.
bp: about 29 °C.
Water (2.5.12): maximum 0.02 per cent.
Residue on evaporation: maximum 0.0003 per cent.
Minimum transmittance (2.2.25), determined using water \( R \) as compensation liquid: 50 per cent at 210 nm, 85 per cent at 220 nm, 98 per cent at 240 nm and at higher wavelengths.

2-Methylbut-2-ene. \( \text{C}_5\text{H}_{10} \) (\( M \), 70.1). 1055400. [513-35-9].
A very flammable liquid, practically insoluble in water, miscible with alcohol.
bp: 37.5 °C to 38.5 °C.

**Methyl caprate.** 1054000.
See Methyl decanoate \( R \).

**Methyl caprylate.** \( \text{C}_9\text{H}_{18}O_2 \) (\( M \), 158.2). 1120400. [111-11-5].
Methyl octanoate.
d\(^{20} \): about 0.876.
\( \rho_{20} \): about 1.417.
bp: 193 °C to 194 °C.

**Methylcellulose 450.** 1055500. [9004-67-5].
See Methylcellulose (0345).
The nominal viscosity is 450 mPa·s.

**Methyl cinnamate.** \( \text{C}_9\text{H}_{12}\text{O}_2 \) (\( M \), 162.2). 1099400. [106-70-7].
Methyl hexanoate.
d\(^{20} \): about 0.885.
\( \rho_{20} \): about 1.405.
bp: 150 °C to 151 °C.

**Methyl caprate.** \( \text{C}_9\text{H}_{18}O_2 \) (\( M \), 158.2). 1120400. [111-11-5].
Methyl octanoate.
d\(^{20} \): about 0.876.
\( \rho_{20} \): about 1.417.
bp: 193 °C to 194 °C.

3-O-Methylldopamine hydrochloride. \( \text{C}_9\text{H}_{14}\text{ClNO}_2 \) (\( M \), 203.7). 1055600. [1477-68-5]. 4-(2-Aminoethyl)-2-methoxyphenol hydrochloride.
mp: 215 °C to 215 °C.

**Chromatography.** Examine as prescribed in the monograph on Dopamine hydrochloride (0664), applying 10 µl of a 0.075 g/l solution in methanol \( R \). The chromatogram obtained shows only one principal spot.

4-O-Methylldopamine hydrochloride. \( \text{C}_9\text{H}_{14}\text{ClNO}_2 \) (\( M \), 203.7). 1055700. [645-33-0]. 5-(2-Aminoethyl)-2-methoxyphenol hydrochloride.
mp: 207 °C to 208 °C.

**Chromatography.** Examine as prescribed in the monograph on Dopamine hydrochloride (0664), applying 10 µl of a 0.075 g/l solution in methanol \( R \). The chromatogram obtained shows only one principal spot.

**Methylenebisacrylamide.** \( \text{C}_5\text{H}_{10}\text{N}_2\text{O}_2 \) (\( M \), 1054000). [78-78-4]. Methylenebispropenamide.
A fine, white or almost white powder, slightly soluble in water, soluble in alcohol.
mp: It melts with decomposition at a temperature above 300 °C.

**Methylene blue.** \( \text{C}_16\text{H}_{18}\text{ClN}_3\text{S} \) (\( M \), 300 °C). 1055800. [7220-79-3].
Schultz No. 1038.

**Colour Index No.** 52015.
3,7-Dimethylaminophenothiazin-5-ium chloride.
It occurs in different hydrated forms and may contain up to 22 per cent of water. A dark-green or bronze, crystalline powder, freely soluble in water, soluble in alcohol.

**Methylene chloride.** \( \text{CH}_2\text{Cl}_2 \) (\( M \), 84.9). 1055900. [75-09-2].
Dichloromethane.
A colourless liquid, sparingly soluble in water, miscible with alcohol.
bp: 39 °C to 42 °C.

Methylene chloride used in fluorimetry complies with the following additional requirement.

**Fluorescence.** Under irradiation at 365 nm, the fluorescence (2.2.21) measured at 460 nm in a 1 cm cell is not more intense than that of a solution containing 0.002 ppm of quinine \( R \) in 0.5 M sulphuric acid measured in the same conditions.

**Methylene chloride, acidified.** 1055901.
To 100 ml of methylene chloride \( R \) add 10 ml of hydrochloric acid \( R \), shake, allow to stand and separate the two layers. Use the lower layer.

**Methyl eicosenoate.** \( \text{C}_{21}\text{H}_{40}O_2 \) (\( M \), 324.5). 1120500. [2390-09-2]. (11Z)-eicos-11-enoate.

**Methyl erucate.** \( \text{C}_{23}\text{H}_{44}O_2 \) (\( M \), 300 °C). 1120300. [111-11-5].
A colourless liquid, sparingly soluble in water, miscible with alcohol.

3-O-Methylldopamine hydrochloride. \( \text{C}_9\text{H}_{14}\text{ClNO}_2 \) (\( M \), 203.7). 1055600. [1477-68-5]. 4-(2-Aminoethyl)-2-methoxyphenol hydrochloride.
mp: 215 °C to 215 °C.

**Chromatography.** Examine as prescribed in the monograph on Dopamine hydrochloride (0664), applying 10 µl of a 0.075 g/l solution in methanol \( R \). The chromatogram obtained shows only one principal spot.
**4.1.1. Reagents**

**Methyl ethyl ketone.** C_4H_8O. (M, 72.1). 1054100. [78-93-3]. Ethyl methyl ketone. 2-Butanone.

A clear, colourless, flammable liquid, very soluble in water, miscible with alcohol.

\[d_{20}^0: \text{about } 0.81.
\]

bp: 79 °C to 80 °C.

**Methyl green.** C_{18}H_{25}Cl_{2}N_{3}. (M, 458.5). 1054200. [7114-03-6].

Schulz No. 788.

Colour Index No. 42585.

bp: 195 °C to 197 °C.

**Methyl iodide.** CH_3I. (M, 141.9). 1166400. [74-88-4].

Iodomethane.

**Methyl isobutyl ketone.** C_6H_{12}O. (M, 92.1). 1054301. [111-82-6].

See the information section on general monographs (cover pages).

**Methyl isobutyl ketone R1.** 1054301.

Shake 50 ml of freshly distilled methyl isobutyl ketone R with 0.5 ml of hydrochloric acid R1 for 1 min. Allow the phases to separate and discard the lower phase. Prepare immediately before use.

**Methyl isobutyl ketone R3.** 1054302.

Complies with the requirements for methyl isobutyl ketone R and with the following limits:

- **Chromium:** maximum 0.02 ppm.
- **Copper:** maximum 0.02 ppm.
- **Lead:** maximum 0.1 ppm.
- **Nickel:** maximum 0.02 ppm.
- **Tin:** maximum 0.1 ppm.

**Methyl laurate.** C_{13}H_{26}O_{2}. (M, 214.4). 1054400. [111-81-0].

Methyl dodecanoate.

**Methyl lignocerate.** C_{19}H_{32}O_{2}. (M, 382.7). 1120600. [2442-49-1].

Methyl tetracosanoate.

Flakes.

mp: about 51 °C.

**Methyl linolenate.** C_{19}H_{32}O_{2}. (M, 295.5). 1120700. [112-63-0].

Methyl (9Z,12Z)-octadeca-9,12-dienoate.

\[d_{20}^0: \text{about } 0.87.
\]

\[n_{D}^0: \text{about } 1.431.
\]

mp: about 5 °C.

**Methyl linoleate.** C_{18}H_{32}O_{2}. (M, 294.5). 1120900. [301-00-8].

Methyl (8Z,12Z)-octadeca-9,12-dienoate.

\[d_{20}^0: \text{about } 0.901.
\]

\[n_{D}^0: \text{about } 1.471.
\]

bp: about 207 °C.

**Methyl linolenate.** C_{18}H_{32}O_{2}. (M, 295.5). 1120800. [16326-32-2].

Methyl (6Z,9Z,12Z)-octadeca-6,9,12-trienoate.

**Methyl linolenate.** C_{19}H_{32}O_{2}. (M, 295.5). 1120800. [16326-32-2].

Methyl (6Z,9Z,12Z)-octadeca-6,9,12-trienoate.

**Methyl linolenate.** C_{19}H_{32}O_{2}. (M, 295.5). 1120900. [1731-92-6].

Methyl heptadecanoate.

mp: about 45 °C.

**Methyl lymolenate.** C_{19}H_{32}O_{2}. (M, 295.5). 1158400. [16326-32-2].

Methyl (6Z,9Z,12Z)-octadeca-6,9,12-trienoate.

**Methyl linoleate used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848). The content of methyl linoleate is not less than 97 per cent, calculated by the normalisation procedure.

**Methyl margarate.** C_{18}H_{36}O_{2}. (M, 284.5). 1120900. [1731-92-6].

Methyl heptadecanoate.

White or almost white powder.

mp: 32 °C to 34 °C.

**Methyl margarate used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848). The content of methyl margarate is not less than 97 per cent, calculated by the normalisation procedure.

**Methyl methacrylate.** C_5H_8O_2. (M, 82.1). 1054500. [80-62-6].

Methyl 2-methylprop-2-enolate.

A colourless liquid.
Methyl oleate. C_{19}H_{36}O_{2}. (in light petroleum.
A colourless or slightly yellow liquid, soluble in alcohol and
gas chromatography (water, practically insoluble in alcohol.
Sodium 4′-(dimethylamino)benzoate.
Colour Index No. 13025.
Schultz No. 176.
[547-58-0].

Methyl N'-methylanthranilate. C_{19}H_{13}NO_{2}. (M, 165.2). 1164600. [85-91-6]. Methyl 2-(methylamino)benzoate.
Pale yellow liquid.
d_{20}^{0} : about 1.128.
n_{D}^{10} : about 1.579.
bp: 255 °C to 258 °C.
Methyl N'-methylanthranilate used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (2.2.28) as prescribed in the monograph on Mandarin oil (2355).
Test solution. The substance to be examined.
Content: minimum 97 per cent, calculated by the normalisation procedure.

Methyl myristate. C_{15}H_{30}O_{2}. (M, 242.4). 1054600. [124-10-7]. Methyl tetradecanoate.
Content: minimum 98.0 per cent of C_{15}H_{30}O_{2}, determined by
gas chromatography (2.4.22).
A colourless or slightly yellow liquid, soluble in alcohol and in
light petroleum.
d_{20}^{0} : about 0.87.
n_{D}^{10} : about 1.437.
mp: about 20 °C.

Methyl nervousate. 1144800. [2733-88-2].
See Tetracos-15-enoic acid methyl ester R.

2-Methyl-5-nitroimidazole. C_{6}H_{5}N_{3}O_{2}. (M, 127.1). 1056100. [88054-22-2].
White to light yellow powder.
mp: 252 °C to 254 °C.
Content: minimum 98.0 per cent of C_{6}H_{5}N_{3}O_{2}.

Methyl olate. C_{17}H_{32}O_{2}. (M, 296.4). 1054700. [1120-25-8]. Methyl hexadecanoate.
Content: minimum 98.0 per cent of C_{17}H_{32}O_{2}, determined by
gas chromatography (2.4.22).
A colourless or slightly yellow liquid, soluble in alcohol and in
light petroleum.
d_{20}^{0} : about 0.873.
n_{D}^{10} : about 1.422.
bp: 91 °C to 92 °C.
Methyl palmitate. C_{17}H_{34}O_{2}. (M, 268.4). 1121000. [1120-25-8]. Methyl (9Z)-hexadec-9-enoate.
A white or yellow, crystalline mass, soluble in alcohol and in
light petroleum.
mp: about 30 °C.

Methyl parahydroxybenzoate. 1055000. [99-76-3].
See Methyl parahydroxybenzoate (0409).

Methyl pelargonate. C_{10}H_{20}O_{2}. (M, 172.3). 1143500. [1731-84-6]. Methyl nonanoate.
Clear, colourless liquid.
d_{20}^{0} : about 0.876.
n_{D}^{10} : about 1.451.

Methyl parahydroxybenzoate. 1055000. [99-76-3].
See Methyl parahydroxybenzoate (0409).

Methyl palmitoleate. C_{17}H_{32}O_{2}. (M, 292.4). 1144800. [1120-25-8]. Methyl 9(Z)-octadec-9-enoate.
A white or yellow, crystalline mass, soluble in alcohol and in
light petroleum.
mp: about 30 °C.

Methyl orange solution.

Test for sensitivity. A mixture of 0.1 ml of the methyl
orange solution and 100 ml of carbon dioxide-free water R
is yellow. Not more than 0.1 ml of 1 M hydrochloric acid
is required to change the colour to red.
Colour change: pH 3.0 (red) to pH 4.4 (yellow).

Methyl parahydroxybenzoate. 1055000. [99-76-3].
See Methyl parahydroxybenzoate (0409).

Methyl pelargonate. C_{10}H_{20}O_{2}. (M, 172.3). 1143500. [1731-84-6]. Methyl nonanoate.
Clear, colourless liquid.
d_{20}^{0} : about 0.876.
n_{D}^{10} : about 1.451.

Methyl parahydroxybenzoate. 1055000. [99-76-3].
See Methyl parahydroxybenzoate (0409).

Methyl pelargonate. C_{10}H_{20}O_{2}. (M, 172.3). 1143500. [1731-84-6]. Methyl nonanoate.
Clear, colourless liquid.
d_{20}^{0} : about 0.876.
n_{D}^{10} : about 1.451.

Methyl parahydroxybenzoate. 1055000. [99-76-3].
See Methyl parahydroxybenzoate (0409).

Methyl palmitoleate. C_{17}H_{32}O_{2}. (M, 292.4). 1144800. [1120-25-8]. Methyl 9(Z)-octadec-9-enoate.
A white or yellow, crystalline mass, soluble in alcohol and in
light petroleum.
mp: about 30 °C.
4.1.1. Reagents

**Methylpiperazine.** C₆H₁₀N₂. (M, 100.2). 1056300. [109-01-3].
A colourless liquid, miscible with water and with alcohol.

\[ \Delta \text{d}^{20}_20: \text{about 0.90.} \]
\[ \eta_20^1: \text{about 1.466.} \]
bp: about 138 °C.

**4(4-Methylpiperidino)pyridine.** C₁₀H₁₁N₂. (M, 176.3). 1114400. [80965-30-6].
A clear liquid.
\[ \Delta \text{d}^{20}_20: \text{about 1.565.} \]

**2-Methylpropanol.** C₄H₁₀O. (M, 71.1). 1056500. [78-83-1].
A clear colourless liquid, soluble in water, miscible with alcohol.
\[ \Delta \text{d}^{20}_20: \text{about 0.80.} \]
\[ \eta_15: 1.397 \text{ to } 1.399. \]
bp: about 107 °C.

**2-Methyl-2-propanol.** C₄H₁₀O. (M, 74.1). 1056500. [75-65-0].
1,1-Dimethyl ethyl alcohol. tert-Butyl alcohol.
A clear colourless liquid, soluble in water, miscible with alcohol.
\[ \Delta \text{d}^{20}_20: \text{about 0.86.} \]
\[ \eta_20^0: \text{about 1.441.} \]
mp: about 6 °C.

**Methyl red.** C₁₅H₁₅N₃O₂. (M, 269.3). 1055100. [493-52-7].
Schulz No. 250.
Colours Index No. 13020.
2-(4-Dimethylamino-phenylazo)benzoic acid.

**Methyl red mixed solution.** 1055101.
Dissolve 0.1 g of methyl red R and 50 mg of methylene blue R in 100 ml of alcohol R.

**Methyl red solution.** 1055102.
Dissolve 50 mg in a mixture of 1.86 ml of 0.1 M sodium hydroxide and 50 ml of alcohol R and dilute to 100 ml with water R.

**Test for sensitivity.** To 0.1 ml of the methyl red solution add 100 ml of carbon dioxide-free water R and 0.05 ml of 0.02 M hydrochloric acid. The solution is red. Not more than 0.1 ml of 0.02 M sodium hydroxide is required to change the colour to yellow.

**Colour change:** pH 4.4 (red) to pH 6.0 (yellow).

**Methyl salicylate.** 1146200. [119-36-8].
See Methyl salicylate (0230).

**Methyl stearate.** C₁₉H₃₈O₂. (M, 298.5). 1055200. [112-61-8].

**Methyl octadecanoate.**

Content: minimum 98.0 per cent of C₁₉H₃₈O₂, determined by gas chromatography (2.4.22).
A white or yellow, crystalline mass, soluble in alcohol and in light petroleum.
mp: about 38 °C.

**Methylthymol blue.** C₁₉H₁₇N₂O₅. (M, 384.5). 1158500. [1945-77-3]. Tetrasodium 2,2′,7,7′-tetraethyloxy-3-(3H,2′,1-benzoazathiol-3-yldene)bis[6-hydroxy-2-methyl-5-(1-methylethyl)-3,1-phenoxylenel(methyl)eniniltrilo][tetraacetate S,S-dioxide.

Produces a blue colour with calcium in alkaline solution.

**Methylthymol blue mixture.** 1158501.
A mixture of 1 part of methylthymol blue R and 100 parts of potassium nitrate R.

**Methyl tricosanoate.** C₂₄H₄₆O₂. (M, 368.6). 1111500. [2433-97-8]. Tricosanoic acid methyl ester.

Content: minimum 99.0 per cent of C₂₄H₄₆O₂.
White or almost white crystals, practically insoluble in water, soluble in hexane.
mp: 55 °C to 56 °C.

**Methyl tridecanoate.** C₁₄H₂₉O₂. (M, 228.4). 1121100. [1731-88-0].
A colourless or slightly yellow liquid, soluble in alcohol and in light petroleum.
\[ \Delta \text{d}^{20}_20: \text{about 0.86.} \]
\[ \eta_20^0: \text{about 1.441.} \]
mp: about 6 °C.

**Methyltrimethylsilyl trifluoroacetamide.** C₁₅H₂₇F₃N₅O. (M, 493-52-7). 1055100. [109-01-3].
1-Methylpyrrolidin-2-one.

**Molecular sieve.** 1056600.
Molecular sieve composed of sodium aluminosilicate. It is available as beads with a pore size of 0.4 nm and with a diameter of 2 mm.

**Molecular sieve for chromatography.** 1129700.
A molecular sieve composed of sodium aluminosilicate. The pore size is indicated after the name of the reagent in the tests where it is used. If necessary, the particle size is also indicated.

**Molybdovanadic reagent.** 1056700.
In a 150 ml beaker, mix 4 g of finely powdered ammonium molybdate R and 0.1 g of finely powdered ammonium vanadate R. Add 70 ml of water R and grind the particles until a suspension is obtained.

See the information section on general monographs (cover pages).
using a glass rod. A clear solution is obtained within a few minutes. Add 20 ml of nitric acid R and dilute to 100 ml with water R.

**Monodocosahexaenoin.** C_{25}H_{38}O_{4}. (M, 402.6). 1143600. [124516-13-8]. Monoglyceride of docosahexaenoic acid (C22:6). Glycerol monodocosahexaenoate. (all-2)-Docosa-4,7,10,13,16,19-hexaenoic acid, monoester with propane-1,2,3-triol.

**Mordant black 11.** C_{20}H_{12}N_{3}NaO_{7}S. (M, 461.4). 1056800. [11091-81-2]. Colourless crystals. Storage: in an airtight container, protected from light.

**Mordant black 11 triturate.** 1056801.

Mix 1 g of mordant black 11 R with 99 g of sodium chloride R.

Test for sensitivity. Dissolve 50 mg in 100 ml of water R. The solution is brownish-violet. On addition of 0.3 ml of dilute ammonia R1 the solution turns blue. On the subsequent addition of 0.1 ml of a 10 g/1 solution of magnesium sulphate R, it turns violet.

Storage: in an airtight container, protected from light.

**Mordant black 11 triturate R.** 1056802.

Mix 1.0 g of mordant black 11 R, 0.4 g of methyl orange R and 0.1 g of sodium chloride R.

**Morphine hydrochloride.** 1056900. See *Morphine hydrochloride* (0097).

**Morphine.** C_{17}H_{21}NO. (M, 285.3). 1057000. [110-91-8]. Tetrahydro-1,4-oxazine. A colourless, hygroscopic liquid, flammable, soluble in water and in alcohol.

**Morpholine.** See *Morphine hydrochloride* (0097).

**Morphine hydrochloride.** 1056900. See *Morphine hydrochloride* (0097).

**Myricene.** C_{10}H_{16}. (M, 152.2). 1137000. [91-20-3]. 5-Allyl-1-methoxy-2,3-methylenedioxybenzene.

An oily liquid with a pleasant odour, practically insoluble in water, miscible with alcohol, soluble in glacial acetic acid. It dissolves in solutions of alkali hydroxides.

\[ \delta^20: \text{about } 0.794. \]

\[ \eta^15: \text{about } 1.470. \]

**β-Myrcene used in gas chromatography complies with the following additional test.**

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on *Peppermint oil* (0405).

**Test solution.** The substance to be examined.

The area of the principal peak is not less than 90.0 per cent of the area of all the peaks in the chromatogram obtained.

**Myristic acid.** C_{15}H_{31}O_{2}. (M, 228.4). 1143700. [544-63-8]. Tetradecanoic acid.

Colourless or white or almost white flakes.

mp: about 58.5 °C.

**Myristic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.**

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on *Saw palmetto fruit (1848)*.

The content of myristic acid is not less than 97 per cent, calculated by the normalisation procedure.

**Myristicine.** C_{15}H_{31}O_{5}. (M, 192.2). 1099600. [607-91-0]. 5-Allyl-1-methoxy-2,3-methylenedioxybenzene.

4-Methoxy-6-prop-2-enyl-1,3-benzodioxole.

An oily colourless liquid, practically insoluble in water, slightly soluble in ethanol, miscible with toluene and with xylene.

\[ \delta^20: \text{about } 1.144. \]

\[ \eta^15: \text{about } 1.540. \]

bp: 276 °C to 277 °C.

mp: about 173 °C.

**Chromatography.** Examined as prescribed in the monograph on *Star anise* (1153), the chromatogram obtained shows only one principal spot.

**Myristicine used in gas chromatography complies with the following additional test.**

Assay. Examine by gas chromatography (2.2.28) under the conditions prescribed in the monograph on *Nutmeg oil* (1552).

The content is not less than 95.0 per cent, calculated by the normalisation procedure.

**Myristyl alcohol.** C_{15}H_{31}O. (M, 214.4). 1121300. [112-72-1]. 1-Tetradecanol.

**Naphtalene.** C_{10}H_{8}. (M, 128.2). 1057100. [91-20-3]. White or almost white crystals, practically insoluble in water, soluble in alcohol.

mp: about 80 °C.

**Naphtalene used for liquid scintillation is of a suitable analytical grade.**

**Naphtharson.** C_{14}H_{11}AsN_{2}Na_{2}O_{10}S_{2}. (M, 576.3). 1121400. [3688-92-4]. Thorin. Disodium 4-{[2-arsonophenyl]azo}-3-hydroxynaphthalene-2,7-disulphonate.

A red powder, soluble in water.
Naphtharson solution. 1121401.
A 0.58 g/l solution.
Test for sensitivity. To 50 ml of alcohol R, add 20 ml of water R, 1 ml of 0.05 M sulphuric acid and 1 ml of the naphtharson solution. Titrate with 0.025 M barium perchlorate; the colour changes from orange-yellow to orange-pink.
Storage: protected from light; use within 1 week.
α-Naphthol. C10H8O. (M, 144.2). 1057300. [90-15-3].
A white or almost white, crystalline powder or colourless or white or almost white crystals, darkening on exposure to light, slightly soluble in water, freely soluble in alcohol.
mp: about 95 °C.
Storage: protected from light.
β-Naphthol solution. 1057301.
Dissolve 0.10 g of α-naphthol R in 3 ml of a 150 g/l solution of sodium hydroxide R and dilute to 100 ml with water R. Prepare immediately before use.
β-Naphthol. C10H8O. (M, 144.2). 1057400. [135-19-3].
2-Naphthol.
White or slightly pink plates or crystals, very slightly soluble in water, freely soluble in alcohol.
mp: about 117 °C.
Storage: protected from light.
β-Naphthol solution. 1057401.
Dissolve 5 g of freshly recrystallised β-naphthol R in 40 ml of dilute sodium hydroxide solution R and dilute to 100 ml with water R. Prepare immediately before use.
β-Naphthol solution R1. 1057402.
Dissolve 3.0 mg of β-naphthol R in 50 ml of sulphuric acid R and dilute to 100.0 ml with the same acid. Use the recently prepared solution.
A brownish-red powder or shiny brownish-black crystals, practically insoluble in water, soluble in alcohol and in glacial acetic acid.
Naphtholbenzein solution. 1057601.
A 2 g/l solution in anhydrous acetic acid R.
Test for sensitivity. To 50 ml of glacial acetic acid R add 0.25 ml of the naphtholbenzein solution. The solution is brownish-yellow. Not more than 0.05 ml of 0.1 M perchloric acid is required to change the colour to green.
2,4-Dinitro-1-naphthol, sodium salt.
Orange-yellow powder or crystals, freely soluble in water, slightly soluble in ethanol.
Naphthol yellow S. C10H9N2Na2O8S. (M, 358.2). 1143800. [846-70-8].
Colour Index No. 10316.
8-Hydroxy-5,7-dinitro-2-naphthalenesulphonic acid disodium salt. Disodium 5,7-dinitro-8-oxidonaphthalene-2-sulphonate. Yellow or orange-yellow powder, freely soluble in water.
1-Naphthyl acetate. C10H9O2. (M, 186.2). 1148400. [86-87-3]. (Naphthalen-1-yl) acetate.
White to yellow crystalline powder, very slightly soluble in water, freely soluble in acetone.
mp: about 135 °C.
Naphthylamine. C10H7N. (M, 143.2). 1057700. [134-32-7].
1-Naphthylamine.
A white or almost white, crystalline powder, turning pink on exposure to light and air, slightly soluble in water, freely soluble in alcohol.
mp: about 51 °C.
Storage: protected from light.
It may contain methanol of crystallisation.
A white to yellowish-white powder, soluble in water, slightly soluble in alcohol.
Naphthylethylenediamine dihydrochloride solution. 1057801.
Dissolve 0.1 g of naphthylethylenediamine dihydrochloride R in water R and dilute to 100 ml with the same solvent. Prepare immediately before use.
A white or almost white crystalline powder, slightly soluble in water, soluble in methanol and in dimethylformamide.
mp: about 171 °C.
Absorbance (2.2.25). Naringin dissolved in a 5 g/l solution of dimethylformamide R in methanol R shows an absorption maximum at 283 nm.
A slightly yellow liquid, slight odour of lily and lily of the valley, practically insoluble in water and in glycerol, miscible with alcohol.
αδ20: about 0.876.
αn20: about 1.479.
bp12: 145 °C to 146 °C.
trans-Nerolidol used in gas chromatography complies with the following additional test.
Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Bitter-orange-flower oil (1175), using the substance to be examined as the test solution. The area of the principal peak is not less than 90.0 per cent of the total area of the peaks.
A colourless, oily liquid.
αδ20: about 0.907.
αn20: about 1.460.
bp25: 134 °C.
Neryl acetate used in gas chromatography complies with the following additional test.
Nickel chloride. \( \text{NiCl}_2 \). 

Contains 48 per cent to 52 per cent of aluminium (Al; \( A \) 26.98) and 48 per cent to 52 per cent of nickel (Ni; \( A \) 58.70).

Before use, reduce to a fine powder (180) (2.9.12).

It is practically insoluble in water and soluble in mineral acids.

**Nickel-aluminium alloy.** \( \text{Ni-Al} \). 1058100.

Contains 48 per cent to 52 per cent of aluminium (Al; \( A \) 26.98) and 48 per cent to 52 per cent of nickel (Ni; \( A \) 58.71).

Fine, grey powder, practically insoluble in water, soluble in mineral acids with formation of salts.

**Colorimetric reagents.**

- A 10 g/l solution of ninhydrin R in 100 ml of ethylene glycol monomethyl ether R. Shake gently with 1 g of cation exchange resin R (300 µm to 840 µm) and filter (solution a). Dissolve 0.16 g of stannous chloride R in 100 ml of buffer solution pH 5.5 R (solution b). Immediately before use, mix equal volumes of each solution.

- Nile blue A solution. 1058201.

A 10 g/1 solution in anhydrous acetic acid R.

Test for sensitivity. To 50 ml of anhydrous acetic acid R add 0.25 ml of the Nile blue A solution. The solution is blue. On the addition of 0.1 ml of 0.1 M perchloric acid, the colour changes to blue-green.

**Colour change:** pH 9.0 (blue) to pH 13.0 (red).

**Ninhydrin.** \( \text{C}_9\text{H}_4\text{O}_3\cdot\text{H}_2\text{O} \). (M, 178.1). 1058300. [485-47-2].

1,2,3-Indanetrione monohydrate.

A white or very pale yellow, crystalline powder, soluble in water and in alcohol.

**Storage:** protected from light.

**Ninhydrin and stannous chloride reagent.** 1058301.

Dissolve 0.2 g of ninhydrin R in 4 ml of hot water R, add 5 ml of a 1.6 g/l solution of stannous chloride R, allow to stand for 30 min, then filter and store at a temperature of 2 °C to 8 °C. Immediately before use dilute 2.5 ml of the solution with 5 ml of water R and 45 ml of 2-propanol R.

**Ninhydrin and stannous chloride reagent R1.** 1058302.

Dissolve 4 g of ninhydrin R in 100 ml of ethylene glycol monomethyl ether R. Shake gently with 1 g of cation exchange resin R (300 µm to 840 µm) and filter (solution a). Dissolve 0.16 g of stannous chloride R in 100 ml of buffer solution pH 5.5 R (solution b). Immediately before use, mix equal volumes of each solution.

**Ninhydrin solution.** 1058303.

A 2 g/l solution of Ninhydrin R in a mixture of 5 volumes of dilute acetic acid R and 95 volumes of butanol R.

**Ninhydrin solution R1.** 1058304.

Dissolve 1.0 g of ninhydrin R in 50 ml of alcohol R and add 10 ml of glacial acetic acid R.

**Ninhydrin solution R2.** 1058305.

Dissolve 3 g of ninhydrin R in 100 ml of a 45.5 g/l solution of sodium metabisulphite R.

**Ninhydrin solution R3.** 1058306.

A 4 g/l solution in a mixture of 5 volumes of anhydrous acetic acid R and 95 volumes of butanol R.

**Nitrazepam.** 1143900. [146-225].

See Nitrazepam (0415).

**Nitric acid.** \( \text{HNO}_3 \). (M, 63.0). 1058400. [7697-37-2].

Content: 63.0 per cent m/m to 70.0 per cent m/m of \( \text{HNO}_3 \).

A clear, colourless or almost colourless liquid, miscible with water.

\( \rho_{20}^0 \): 1.384 to 1.416.

A 10 g/l solution is strongly acid and gives the reaction of nitrates (2.3.1).

**Appearance.** Nitric acid is clear (2.2.1) and not more intensely coloured than reference solution \( Y_6 \) (Method II, 2.2.2).

**Chlorides (2.4.4).** To 5 g add 10 ml of water R and 0.3 ml of silver nitrate solution R2 and allow to stand for 2 min protected from light. Any opalescence is not more intense than that of a standard prepared in the same manner using 13 ml of water R, 0.5 ml of nitric acid R, 0.5 ml of chloride standard solution (5 ppm Cl) R and 0.3 ml of silver nitrate solution R2 (0.5 ppm).
4.1.1. Reagents

Sulphates (2.4.13). Evaporate 10 g to dryness with 0.2 g of sodium carbonate R. Dissolve the residue in 15 ml of distilled water R. The solution complies with the limit test for sulphates (2 ppm). Prepare the standard using a mixture of 2 ml of sulphate standard solution (10 ppm SO₄) R and 13 ml of distilled water R.

Arsenic (2.4.2). Gently heat 50 g with 0.5 ml of sulphuric acid R until white fumes begin to evolve. To the residue add 1 ml of a 100 g/l solution of hydroxylamine hydrochloride R and dilute to 2 ml with water R. The solution complies with limit test A for arsenic (0.02 ppm). Prepare the standard using 1.0 ml of arsenic standard solution (1 ppm As) R.

Heavy metals (2.4.8). Dilute 10 ml of the solution prepared for the limit test for iron to 20 ml with water R. 12 ml of the solution complies with limit test A for heavy metals (2 ppm). Prepare the standard using lead standard solution (2 ppm Pb) R.

Iron (2.4.9). Dissolve the residue from the determination of sulphated ash in 1 ml of dilute hydrochloric acid R and dilute to 50 ml with water R. 5 ml of the solution diluted to 10 ml with water R complies with the limit test for iron (1 ppm).

Sulphated ash. Carefully evaporate 100 g to dryness. Moisten the residue with a few drops of sulphuric acid R and heat to dull red. The residue does not exceed 0.001 per cent.

Assay. To 1.50 g add about 50 ml of water R and titrate with 1 M sodium hydroxide, using 0.1 ml of methyl red solution R as indicator.

1 ml of 1 M sodium hydroxide is equivalent to 63.0 mg of HNO₃.

Storage: protected from light.

Nitric acid, cadmium- and lead-free. 1058401.

Complies with the requirements prescribed for Nitric acid R and with the following additional test.

Test solution. To 100 g add 0.1 g of anhydrous sodium carbonate R and evaporate to dryness. Dissolve the residue in water R heating slightly, and dilute to 50.0 ml with the same solvent.

Cadmium: maximum 0.1 ppm of cadmium (Cd) determined by atomic absorption spectrometry (Method II, 2.2.23) measuring the absorbance at 228.8 nm using a cadmium hollow-cathode lamp and an air-acetylene flame.

Lead: maximum 0.1 ppm of lead (Pb) determined by atomic absorption spectrometry (Method II, 2.2.23) measuring the absorbance at 283.3 nm or 217.0 nm using an air-acetylene or air-propane flame.

Nitric acid, dilute. 1058402.

Contains about 125 g/l of HNO₃ (M, 63.0).

Dilute 20 g of nitric acid R to 100 ml with water R.

Nitric acid, dilute R1. 1058407.

Dilute 40 g of nitric acid R to 100 ml with water R.

Nitric acid, heavy metal-free. 1058404.

Complies with the requirements prescribed for nitric acid R and with the following maximum contents of heavy metals:

As: 0.005 ppm;
Cd: 0.005 ppm;
Cu: 0.001 ppm;
Fe: 0.02 ppm;
Hg: 0.002 ppm;
Ni: 0.005 ppm;
Pb: 0.001 ppm;
Zn: 0.01 ppm.

Nitric acid, lead-free. 1058403.

Complies with the requirements prescribed for Nitric acid R and with the following additional test:

To 100 g add 0.1 g of anhydrous sodium carbonate R and evaporate to dryness. Dissolve the residue in water R, heating slightly, and dilute to 50.0 ml with the same solvent. Determine the lead content by atomic absorption spectrometry (Method II, 2.2.23) measuring the absorbance at 283.3 nm or 217.0 nm using a lead hollow-cathode lamp and an air-acetylene flame. It contains not more than 0.1 ppm of lead (Pb).

Nitric acid, lead-free R1. 1058405.

Nitric acid R containing not more than 1 µg/kg of lead.

Nitric acid, lead-free, dilute. 1058406.

Dilute 5 g of lead-free nitric acid R1 to 100 ml with deionised distilled water R.

Nitric acid, nickel-free. 1058408.

It complies with the requirements described for nitric acid R with the following additional requirement.

Nickel: maximum 0.005 ppm.

Nitric acid, fuming. 1058500. [52583-42-3].

A clear, slightly yellowish liquid, fuming on contact with air. d₂₀¹: about 1.5.

Nitroletriacetic acid. C₆H₆N₂O₂ (M, 191.1). 1137400. [139-13-9].

White or almost white crystalline powder, practically insoluble in water and in most organic solvents. mp: about 240 °C, with decomposition.

Nitroaniline. C₆H₆N₂O₂ (M, 138.1). 1058600. [100-01-6].

Nitrobenzaldehyde. C₇H₅NO₃ (M, 151.1). 1058700. [552-89-6].

Nitrobenzaldehyde. C₇H₅NO₃ (M, 151.1). 1058700. [552-89-6].

Yellow needles, slightly soluble in water, freely soluble in alcohol, volatile in steam. mp: about 42 °C.

Nitrobenzaldehyde paper. 1058701.

Dissolve 0.2 g of nitrobenzaldehyde R in 10 ml of a 200 g/l solution of sodium hydroxide R. Use the solution within 1 h. Immerse the lower half of a slow filter paper strip 10 cm long and 0.8 cm to 1 cm wide. Absorb the excess reagent between two sheets of filter paper. Use within a few minutes of preparation.

Nitrobenzaldehyde solution. 1058702.

Add 0.12 g of powdered nitrobenzaldehyde R to 10 ml of dilute sodium hydroxide solution R; allow to stand for 10 min shaking frequently and filter. Prepare immediately before use.
Nitrobenzene. $\text{C}_6\text{H}_5\text{NO}_2$ ($M$, 123.1). 1058800. [98-95-3].
A colourless or very slightly yellow liquid, practically insoluble in water, miscible with alcohol.
bp: about 211 °C.

Dinitrobenzene. To 0.1 ml add 5 ml of acetone $R$, 5 ml of water $R$ and 5 ml of strong sodium hydroxide solution $R$. Shake and allow to stand. The upper layer is almost colourless.

4-Nitrobenzyl chloride. $\text{C}_7\text{H}_6\text{ClNO}_2$. ($M$, 167.1). 1144000. [62-23-7].
Yellow crystals. mp: about 240 °C.

Nitrobenzoyl chloride. $\text{C}_6\text{H}_5\text{CNO}_2$. ($M$, 185.6). 1058900. [122-04-3]. 4-Nitrobenzyl chloride. Yellow crystals or a crystalline mass, decomposing in moist air, completely soluble in sodium hydroxide solution giving a yellowish-orange colour.

mp: about 72 °C.

Nitrobenzyl chloride. $\text{C}_6\text{H}_5\text{CNO}_2$. ($M$, 171.6). 1059000. [100-14-1]. 4-Nitrobenzyl chloride. Pale-yellow crystals, lachrymatory, practically insoluble in water, very soluble in alcohol.

mp: about 110 °C.

4-(4-Nitrobenzyl)pyridine. $\text{C}_{12}\text{H}_{10}\text{N}_2\text{O}_2$. ($M$, 214.2). 1101900. [1083-48-3].
Yellow powder. mp: about 70 °C.

Nitrochromic reagent. 1059100.
Dissolve 0.7 g of potassium dichromate $R$ in nitric acid $R$ and dilute to 10 ml with the same acid.

Nitroethane. $\text{C}_2\text{H}_5\text{NO}_2$. ($M$, 75.1). 1059200. [79-24-3].
A clear, oily, colourless liquid. bp: about 110 °C.

Nitrofurantoin. 1099700. [67-20-9].
See Nitrofurantoin (1001).

(5-Nitro-2-furylmethylene dicacetate. $\text{C}_9\text{H}_9\text{NO}_7$. 1099900. [92-55-7]. Nitrofurural dicacetate. 5-Nitrofururylidene dicacetate.
Yellow crystals. mp: about 90 °C.

Nitrogen. $\text{N}_2$ ($M$, 28.01). 1059300. [7727-37-9].
Nitrogen, washed and dried.

Nitrogen $R$. 1059400.
Content: minimum 99.999 per cent $V/V$ of $\text{N}_2$.
Carbon monoxide: less than 5 ppm.
Oxygen: less than 5 ppm.

Nitrogen for chromatography. 1059500.
Content: minimum 99.95 per cent $V/V$ of $\text{N}_2$.

Nitrogen gas mixture. 1136900.
Nitrogen $R$ containing 1 per cent $V/V$ of each of the following gases: carbon dioxide $R$, carbon monoxide $R$ and oxygen $R$.

Nitro oxide. $\text{N}_2\text{O}$. ($M$, 44.01). 1108500.
Content: minimum 99.99 per cent $V/V$ of $\text{N}_2\text{O}$.
Carbon monoxide: less than 1 ppm.

Nitrogen monoxide. NO. ($M$, 30.01). 1108300.
Content: minimum 98.0 per cent $V/V$ of NO.

Nitrogen, oxygen-free. 1059500.
Nitrogen $R$ which has been freed from oxygen by passing it through alkaline pyrogallol solution $R$.

Nitromethane. $\text{CH}_3\text{NO}_2$. ($M$, 161.0). 1059700. [75-52-5].
A clear, colourless, oily liquid, slightly soluble in water, miscible with alcohol.

$\delta^\text{D} = 1.132$ to 1.134.
$n^\text{D} = 1.381$ to 1.383.
Distillation range (2.2.11). Not less than 95 per cent distils between 100 °C and 103 °C.

Nitro-molybdovanadic reagent. 1060100.
Solution I. Dissolve 10 g of ammonium molybdate $R$ in water $R$, add 1 ml of ammonia $R$ and dilute to 100 ml with water $R$.

Solution II. Dissolve 2.5 g of ammonium vanadate $R$ in hot water $R$, add 14 ml of nitric acid $R$ and dilute to 500 ml with water $R$.

To 96 ml of nitric acid $R$ add 100 ml of solution I and 100 ml of solution II and dilute to 500 ml with water $R$.

4-Nitrophenol. $\text{C}_6\text{H}_5\text{NO}_3$. ($M$, 139.1). 1146400. [100-02-7]. $p$-Nitrophenol.
Content: minimum 95 per cent of $\text{C}_6\text{H}_5\text{NO}_3$.
Colourless or slightly yellow powder, sparingly soluble in water and in methanol.

mp: about 114 °C.

$\gamma$-Nitrosodiethanolamine. $\text{C}_6\text{H}_5\text{NO}_3$. ($M$, 134.1). 1129800. [1116-54-7]. 2,2′-Nitrosoiminodiethanol. A yellow liquid, miscible with ethanol.

$n^\text{D} = 1.485$.
bp: about 125 °C.

Nitrosodipropylamine. $\text{C}_6\text{H}_{14}\text{N}_2\text{O}$. ($M$, 130.2). 1099900. [621-64-7]. Dipropylnitrosamine. Liquid, soluble in ethanol and in strong acids.

$\delta^\text{D} = 0.915$.
bp: about 78 °C.
Appropriate grade for chemiluminescence determination.

Nitrosodipropylamine solution. 1099901.
Inject 78.62 g of ethanol $R$ through the septum of a vial containing nitrosodipropylamine $R$. Dilute 1/100 in ethanol $R$ and place 0.5 ml aliquots in crimp-sealed vials.

Storage: in the dark at 5 °C.

$p$-Nitro-tetrazolium blue.
Crystals, soluble in methanol, giving a clear, yellow solution.
mp: about 189 °C, with decomposition.

Nitrous oxide. $\text{N}_2\text{O}$. ($M$, 44.01). 1108500.
Content: minimum 99.99 per cent $V/V$ of $\text{N}_2\text{O}$.
Carbon monoxide: less than 1 ppm.

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Nonivamide. C_{17}H_{27}NO_{3}. (M, 293.4). 1148500. [2444-46-4]. |N\{4-Hydroxy-3-methoxyphenyl\}methyl\}nonanamide.

- White or almost white, crystalline powder, practically insoluble in cold water, freely soluble in ethanol.
- Nonivamide used in the test for nonivamide in Capsicum (1859) complies with the following additional requirement.
- Assay. Examine by liquid chromatography (2.2.29) as prescribed in the monograph on Capsicum (1859). The content of nonivamide is not less than 98.0 per cent, calculated by the normalisation procedure.

Nonylamine. C_{9}H_{21}N. (M, 143.3). 1139800. [112-20-9]. 1-Aminononane.

- Corrosive, colourless, clear liquid. a_{D}^{20}: about 0.788.
- n_{D}^{20}: about 1.433.

Nordazepam. C_{21}H_{21}ClN_{2}O. (M, 347.8). 1060200. [1088-11-5]. 7-Chloro-2,3-dihydro-5-phenyl-1H-1,4-benzodiazepin-2-one.

- A white or pale yellow, crystalline powder, practically insoluble in water, slightly soluble in alcohol.
- mp: about 216 °C.

Octadecyldimethylamine. C_{25}H_{45}N. (M, 369.5). 1114600. [116-49-3]. 2,3-Dimethylamine.

- A colourless liquid, practically insoluble in water, miscible with alcohol, soluble in toluene.
- a_{D}^{20}: about 0.891.
- n_{D}^{20}: about 1.459.

Oleic acid. C_{18}H_{36}O. (M, 278.5). 1060900. (9Z)-9-Octodec-9-enoic acid.

- A yellowish or white powder or granules, practically insoluble in water, very soluble in methylene chloride, soluble in ethanol.
- mp: about 80 °C.

Oleamide. C_{18}H_{35}NO. (M, 281.5). 1060800. (Z)-Z-9-Octadec-9-enoamide.

- Shiny crystals, sparingly soluble in water and in alcohol, soluble in acids.

Noscapine hydrochloride. 1060500. [912-60-7]. See Noscapine hydrochloride (0515).

Octan-1-amine. C_{8}H_{17}NH. (M, 118.2). 1150400. [124-13-0]. Octylamine.

- Oil, colourless liquid. Practically insoluble in water.

Octanol. C_{8}H_{17}O. (M, 112.2). 1150500. [124-13-0]. Octyl alcohol.

- mp: 49 °C to 55 °C.

- Octanal used in gas chromatography complies with the following additional test.
- Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Sweet orange oil (1811). The content is not less than 99 per cent, calculated by the normalisation procedure.

Octane. C_{8}H_{18}. (M, 114.2). 1166500. [111-65-9]. n-Octane.

- 1-Octanol. C_{8}H_{18}O. (M, 130.2). 1060700. [111-87-5]. 1-Octanol. Caprylic alcohol.

- A colourless liquid, practically insoluble in water, miscible with alcohol.
- a_{D}^{20}: about 0.828.
- bp: about 195 °C.

3-Octanone. C_{8}H_{16}O. (M, 128.2). 1114600. [106-68-3]. Ethylpentylketone.

- A colourless liquid with a characteristic odour.
- a_{D}^{20}: about 0.822.

3-Octanone used in gas chromatography complies with the following additional test.

- Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Lavender oil (1338).

Test solution. The substance to be examined.

The area of the principal peak is not less than 98.0 per cent of the area of all the peaks in the chromatogram obtained.

Octoxinol 10. C_{8}H_{16}O_{11} (average). (M, 647). 1060800. [9002-93-3]. α-[4-{(1,1,3,3-Tetramethylbutyl)phenyl}ω-hydroxy(polyoxyethylene).

- A clear, pale-yellow, viscous liquid, miscible with water, with acetone and with alcohol, soluble in toluene.

Storage: in an airtight container.

Ocynamine. C_{18}H_{35}N. (M, 292.5). 1150500. [111-86-4]. Octan-1-amine.

- Colourless liquid. a_{D}^{20}: about 0.782.
- bp: 175 °C to 179 °C.

Oleic acid. C_{18}H_{36}O_{2}. (M, 282.5). 1144100. [112-80-1]. (9Z)-9-Octadec-9-enoic acid.

- See the information section on general monographs (cover pages)

See Olive oil, virgin (0518).
Oxazepam (0778)

Obtained after filtration. Dry at 37 °C for 2 h or until the odour of acetone is no longer present.

Osmium tetroxide solution.

A 2.5 g/l solution in 0.05 M sulphuric acid.

Oxalic acid.

C$_4$H$_2$O$_4$. (M, 126.1). 1061400. [6153-56-6]. Ethanedioic acid dihydrate.

White or almost white crystals, soluble in water, freely soluble in alcohol.

Oxalic acid and sulphuric acid solution. 1061401.

A 50 g/l solution of oxalic acid R in a cooled mixture of equal volumes of sulphuric acid R and water R.

Oxazepam. 1144300. [604-75-1].

See Oxazepam (0778).

Ox brain, acetone-dried. 1061300.

Cut into small pieces a fresh ox brain previously freed from vascular and connective tissue. Place in acetone R for preliminary dehydration. Complete the dehydration by pounding in a mortar 30 g of this material with successive quantities, each of 75 ml, of acetone R until a dry powder is obtained after filtration. Dry at 37 °C for 2 h or until the odour of acetone is no longer present.


Colourless, corrosive liquid.

$\delta$$_{20}^\text{D}$. about 0.85.

n$^\text{D}$. about 1.430.

Oxygen. O$_2$. (M, 32.00). 1108800.

Content: minimum 99.99 per cent V/V of O$_2$.

Nitrogen and argon: less than 100 ppm.

Carbon dioxide: less than 10 ppm.

Carbon monoxide: less than 5 ppm.

Oxygen R1. O$_2$. (M, 32.00). 1137600.

Content: minimum 99 per cent V/V of O$_2$.

Oxytetracycline hydrochloride. 1146500.

See Oxytetracycline hydrochloride (0198).


mp: 678 °C to 680 °C.

Palladium chloride solution. 1061501.

Dissolve 1 g of palladium chloride R in 10 ml of warm hydrochloric acid R. Dilute the solution to 250 ml with a mixture of equal volumes of dilute hydrochloric acid R and water R. Dilute this solution immediately before use with 2 volumes of water R.

Palmitic acid. C$_{16}$H$_{32}$. (M, 256.4). 1061600. [57-10-3]. Hexadecanoic acid.

White or almost white, crystalline scales, practically insoluble in water, freely soluble in hot alcohol.

mp: about 63 °C.

Chromatography. Examine as prescribed in the monograph on Chloramphenicol palmitate (0473). The chromatogram shows only one principal spot.

Palmitic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848). The content of palmitic acid is not less than 98 per cent, calculated by the normalisation procedure.

Palmitoleic acid.

C$_{16}$H$_{30}$. (M, 254.4). 1144400. [373-49-9]. (Z)-Hexadec-9-enoic acid.

Clear, colourless liquid.

bp: about 162 °C.

Palmitoleic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848). The content of palmitoleic acid is not less than 98 per cent, calculated by the normalisation procedure.

Palmityl alcohol.

C$_{16}$H$_{34}$. (M, 242.4). 1156100. [36653-82-4]. Cetyl alcohol. 1-Hexadecanol.

mp: about 48 °C.

Content: minimum 96 per cent of C$_{16}$H$_{34}$O.

Pancreas powder. 1061700.

See Pancreas powder (0350).
Papain. 1150700. [9001-73-4].
A proteolytic enzyme obtained from the latex of the green fruit and leaves of Carica papaya L.

Papaverine hydrochloride. 1061800. [61-25-6].
See Papaverine hydrochloride (0102).

Paper chromatography performance test solutions. 1150800.
Test solution (a). Sodium pertechnetate (99mTc) injection (fission) (0283) or Sodium pertechnetate (99mTc) injection (non-fission) (0283).
Test solution (b). In a closed vial mix 100 µl of a 5 g/l solution of stannous chloride R in 0.05 M hydrochloric acid and 100 MBq to 200 MBq of Sodium pertechnetate (99mTc) injection (fission) (0283) or Sodium pertechnetate (99mTc) injection (non-fission) (0283) in a volume not exceeding 2 ml.

Paper for chromatography. 1150900.
Pure cellulose grade thin paper with a smooth surface and a thickness of about 0.2 mm.

Chromatographic separation. To 2 strips of paper for chromatography R apply separately 2-5 µl of test solution (a) and test solution (b) of paper chromatography performance test solutions R. Develop over a pathlength of 3/4 of the paper height, using a mixture of equal volumes of methanol R and water R. Allow to dry and determine the distribution of radioactivity using a suitable detector. The paper is not satisfactory, unless the chromatogram obtained with test solution (a) shows a single radioactivity spot with an Rf value in the range 0.8-1.0 and the chromatogram obtained with test solution (b) shows a single radioactivity spot at the application point (Rf value in the range 0.0-0.1).

Paracetamol. 1061900. [103-90-2].
See Paracetamol (0049).

Paracetamol, 4-aminophenol-free. 1061901.
Recrystallise paracetamol R from water R and dry in vacuo at 70 °C; repeat the procedure until the product complies with the following test: dissolve 5 g of the dried substance in a mixture of equal volumes of methanol R and water R and dilute to 100 ml with the same mixture of solvents. Add 1 ml of a freshly prepared solution containing 10 g/l of sodium nitroprusside R and 10 g/l of antihydros sodium carbonate R, mix and allow to stand for 30 min protected from light. No blue or green colour is produced.

Paraffin, liquid. 1062000. [8042-47-5].
See Liquid paraffin (0239).

Paraffin, white soft. 1062100.
A semi-liquid mixture of hydrocarbons obtained from petroleum and bleached, practically insoluble in water and in alcohol, soluble in light petroleum R1, the solution sometimes showing a slight opalescence.

Paraldehyde. 1151000. [123-63-7].
See Paraldehyde (0351).

Pararosaniline hydrochloride. C19H18ClN3. (M, 323.8). 1062200. [569-61-9].
Schultz No. 779.
Colour Index No. 42500.

4-[bis(4-Aminophenyl)methylene]cyclohexa-2,5-dieniminium chloride.
A bluish-red, crystalline powder, slightly soluble in water, soluble in ethanol. Solutions in water and ethanol are deep-red; solutions in sulphuric acid and in hydrochloric acid are yellow.

mp: about 270 °C, with decomposition.

Decolourised pararosaniline solution. 1062201.
To 0.1 g of pararosaniline hydrochloride R in a ground-glass-stoppered flask add 60 ml of water R and a solution of 1.0 g of anhydrous sodium sulphite R or 2.0 g of sodium sulphite R or 0.75 g of sodium metabisulphite R in 10 ml of water R. Slowly and with stirring add 6 ml of dilute hydrochloric acid R, stopper the flask and continue stirring until dissolution is complete. Dilute to 100 ml with water R. Allow to stand for 12 h before use.

Storage: protected from light.

(4E)-(1αR,7αS,10αS,10βS)-1α,5-Dimethyl-8-methylene-2,3,6,7,8,10α-octahydro-oxireno[9,10]cycloeca[1,2-b]furan-9(1αH)-one. (E)-3,5-S,S,4,5-Epoxygermacra-1(10),11(13)-dieno-12(6)-lactone.
A white or almost white, crystalline powder, very slightly soluble in water, very soluble in methylene chloride, soluble in methanol.

[(12R)-12-µg/ml.]

Penicillinase solution. 1062300.
Dissolve 10 g of casein hydrolysate, 2.72 g of penicillinase in penicillinase solution is approximately 4 µg/ml. The Michaelis constant for benzylpenicillin of the absorption maximum at 214 nm.

Penicillinase solution.

Penicillinase solution.

Penicillinase solution.

Penicillinase solution.

Penicillinase solution.

Penicillinase solution.

Penicillinase solution.

Penicillinase solution.
2,2'-bis(Hydroxyethyl)propane-1,3-diol tetrakis[3,5-di(1,1-dimethylethyl)-4-hydroxyphenyl]propionate.
A white to slightly yellow, crystalline powder, practically insoluble in water, very soluble in acetone, soluble in methanol, slightly soluble in hexane.
mp: 110 °C to 125 °C.
α-form: 120 °C to 125 °C.
β-form: 110 °C to 115 °C.

Pentafluoropropanoic acid. C₃HF₅O₂. (Mp, 1175.0). 1065101. [422-64-0].
Clear, colourless liquid.
d₂₀: about 1.651. 
nD: about 1.284.
bp: about 97 °C.

A clear, colourless, flammable liquid, very slightly soluble in water, miscible with acetone and with ethanol.
d₂₀: about 0.63.
nD: about 1.359.
bp: about 36 °C.

Pentane used in spectrophotometry complies with the following additional requirement.
Minimum transmittance (2.2.25), determined using water R as compensation liquid: 20 per cent at 200 nm, 50 per cent at 210 nm, 85 per cent at 220 nm, 93 per cent at 230 nm, 98 per cent at 240 nm.

1,2-Pentanediol. C₅H₁₀O₂. (Mp, 104.2). 1155800. [5343-92-0].
(2RS)-Pentane-1,2-diol.
d₂₀: about 0.971.
nD: about 1.439.
bp: about 201 °C.

Colourless liquid, sparingly soluble in water, miscible with alcohol.
nD: about 1.410.
bp: about 137 °C.

tert-Pentyl alcohol. C₅H₁₀O. (Mp, 88.1). 1062700. [75-85-4].
 tert- Amyl alcohol. 2-Methyl-2-butanol.
A volatile, flammable liquid, freely soluble in water, miscible with alcohol and with glycerol.
d₂₀: about 0.81.
Distillation range (2.2.11). Not less than 95 per cent distils between 100 °C and 104 °C.
Storage: protected from light.

Pepsin powder. 1062800. [9001-75-6].
See Pepsin powder (0682).

Perchloric acid. HClO₄. (Mp, 100.5). 1062900. [7601-90-3].
Content: 70.0 per cent m/m to 73.0 per cent m/m of HClO₄. 
A clear, colourless liquid, miscible with water.
d₂₀: about 1.7.
Assay. To 2.50 g add 50 ml of water R and titrate with 1 M sodium hydroxide, using 0.1 ml of methyl red solution R as indicator.
1 ml of 1 M sodium hydroxide is equivalent to 100.5 mg of HClO₄.

Perchloric acid solution. 1062901.
Dilute 8.5 ml of perchloric acid R to 100 ml with water R.

Periodic acetic acid solution. 1063000.
Dissolve 0.446 g of sodium periodate R in 2.5 ml of a 25 per cent V/V solution of sulphuric acid R. Dilute to 100.0 ml with glacial acetic acid R.

Periodic acid. H₃IO₆. (Mp, 227.9). 1108900. [10450-60-9].
Crystals, freely soluble in water and soluble in alcohol.
mp: about 122 °C.

Permethrin. C₂₁H₂₀Cl₂O₃. (Mp, 391.3). 1130000. [52645-1].
mp: 34 °C to 35 °C. A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Peroxide test strips. 1147800.
Use commercial test strips with a suitable scale in the range from 0 ppm to 25 ppm peroxide.

Perylene. C₁₃H₁₂. (Mp, 252.3). 1130100. [198-55-0].
Dibenz(de,f)anthracene.
Orange powder.
mp: about 279 °C.

Petroleum, light. 1063100. [8032-32-4]. Petroleum ether 50-70 °C.
A clear, colourless, flammable liquid without fluorescence, practically insoluble in water, miscible with ethanol (96 per cent).
d₂₀: 0.661 to 0.664.

Distillation range (2.2.11): 50 °C to 70 °C.

Petroleum, light R1. 1063101. Petroleum ether 40-60 °C.
Complies with the requirements prescribed for light petroleum R, with the following modifications.
d₂₀: 0.630 to 0.656.
Distillation range (2.2.11): 40 °C to 60 °C.
It does not become cloudy at 0 °C.

Petroleum, light R2. 1063102. Petroleum ether 30-40 °C.
Complies with the requirements prescribed for light petroleum R, with the following modifications.
d₂₀: 0.620 to 0.630.
Distillation range (2.2.11): 30 °C to 40 °C.
It does not become cloudy at 0 °C.

Petroleum, light R3. 1063103. Petroleum ether 100-120 °C.
Complies with the requirements prescribed for light petroleum R, with the following modifications.
d₂₀: 0.720.
Distillation range (2.2.11): 100 °C to 120 °C.
Water (2.5.12): maximum 0.03 per cent.

Petroleum, light R4. 1063104. Petroleum ether 80-100 °C.
Complies with the requirements prescribed for light petroleum R, with the following modifications.
Distillation range (2.2.11): 80 °C to 100 °C.
d₂₀: about 0.70.

4.1.1. Reagents

**Phenol**. \( \text{C}_6\text{H}_5\text{O} \). \( M_r 94.11 \). 1063600. [85-01-8].

A white or almost white powder, practically insoluble in water, sparingly soluble in alcohol.

mp: about 100 °C.

**Phenol red**. \( \text{C}_18\text{H}_23\text{Cl}_2\text{NO} \). mp: about 1.471.

Dissolve 0.1 g of phenol red solution R2 in 1.5 ml of dilute sodium hydroxide solution R in 235 ml of water R; add 105 ml of dilute sodium hydroxide solution R and 135 ml of dilute acetic acid R. Add 25 ml of solution I to solution II. If necessary, adjust the pH of the mixture to 4.7.

**Phenol red solution R3.** 1063604.

Solution I. Dissolve 33 mg of phenol red R in 1.5 ml of dilute sodium hydroxide solution R and dilute to 50 ml with water R.

**Phenol red solution R2.** 1063603.

Solution I. Dissolve 33 mg of phenol red R in 1.5 ml of dilute sodium hydroxide solution R and dilute to 100 ml with water R.

**Phenolphthalein.** \( \text{C}_{20}\text{H}_{14}\text{O}_4 \). \( M_r 340.3 \). 1063700. [77-09-8]. 2-Phenoxyethanol.

A clear, colourless, oily liquid, slightly soluble in water, freely soluble in alcohol.

mp: about 138 °C.

**Phenolphthalein solution.** Dissolve 50 mg of ammonium sulphate R in 1.5 ml of dilute sodium hydroxide solution R and dilute to 100 ml with water R.

**Phenolphthalein paper.** 1063704.

Immerse strips of filter paper for a few minutes in phenolphthalein solution R. Allow to dry.

mp: about 98 °C.

**Phenolphthalein solution R1.** 1063703.

Dissolve 0.1 ml of the phenolphthalein solution R in 235 ml of water R; add 25 ml of solution I to solution II. If necessary, adjust the pH of the mixture to 4.7.

**Phenolphthalein solution R2.** 1063702.

Dissolve 0.1 g of phenolphthalein R in 80 ml of alcohol R and dilute to 100 ml with water R.

**Phenolphthalein solution R3.** 1063601.

Dissolve 0.1 g of phenolphthalein R in a mixture of 2.82 ml of 0.1 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R.

**Phenolphthalein solution R4.** 1063602.

Dissolve 33 mg of phenol red R in 1.5 ml of dilute sodium hydroxide solution R and dilute to 100 ml with water R.

**Phenolphthalein solution R5.** 1063705.

Dissolve 25 mg of ammonium sulphate R in 235 ml of water R; add 105 ml of dilute sodium hydroxide solution R and 135 ml of dilute acetic acid R. Add 25 ml of solution I to solution II. If necessary, adjust the pH of the mixture to 4.7.

**Phenol.** 1062500. [108-95-2].

See Phenol (0631).

**Phenothiazine.** \( \text{C}_{10}\text{H}_{8}\text{N}_3\text{Cl} \). \( M_r 229.69 \). 1063900. N-(2-Chloroethyl)-2-methyl-2-phenoxyethyl benzamide hydrochloride.

Content: 97.0 per cent to the equivalent of 103.0 per cent of \( \text{C}_{10}\text{H}_{8}\text{Cl}_2\text{N}_3 \), calculated with reference to the dried substance.

A white or almost white, crystalline powder, sparingly soluble in water, freely soluble in alcohol.

mp: about 138 °C.

**Phenoxybenzamine hydrochloride.** \( \text{C}_{12}\text{H}_{11}\text{NO} \). \( M_r 203.23 \). 1065500. [122-99-6]. 2-Phenoxybenzenamine. 2-Aminophenyl phenyl ether.

**Phenoxyethanol.** \( \text{C}_8\text{H}_{10}\text{O}_2 \). \( M_r 124.17 \). 1064000. \( \text{C}_8\text{H}_{10}\text{O}_2 \). [122-59-8]. 2-Phenoxyethanol.

A white or almost white powder, practically insoluble in water, freely soluble in alcohol.

mp: about 100 °C.

**Phenoxyethanol.** \( \text{C}_8\text{H}_{10}\text{O}_2 \). \( M_r 124.17 \). 1064000. \( \text{C}_8\text{H}_{10}\text{O}_2 \). [122-59-8]. 2-Phenoxyethanol.

A white or almost white powder, practically insoluble in water, freely soluble in alcohol.

mp: about 100 °C.
Phenylalanine. 1064100. [63-91-2].
See Phenylalanine (0782).

p-Phenylene diamine dihydrochloride. C7H5ClN2. (M, 181.1). 1064200. [615-28-1]. 1,4-Diaminobenzene dihydrochloride.
A crystalline powder or white or slightly coloured crystals, turning reddish on exposure to air, freely soluble in water, slightly soluble in alcohol.


Content: minimum 99 per cent of C7H9NO2.

Phenylhydrazine hydrochloride. C7H7N2Cl. (M, 144.6). 1064400. [59-88-1]. A white or almost white, crystalline powder, becoming brown.

Phenylhydrazine solution. 1064501.
Dissolve 0.9 g of phenylhydrazine hydrochloride R in 50 ml of water R. Decolourise with activated charcoal R and filter. To the filtrate add 30 ml of hydrochloric acid R and dilute to 250 ml with water R.

Phenylhydrazine-sulphuric acid solution. 1064502.
Dissolve 65 mg of phenylhydrazine hydrochloride R, previously recrystallised from alcohol (85 per cent V/V) R, in a mixture of 80 volumes of water R and 170 volumes of sulphuric acid R and dilute to 100 ml with the same mixture of solvents. Prepare immediately before use.

Phenyl isothiocyanate. C7H5NS. (M, 135.2). 1121500. [103-72-0]. A liquid, insoluble in water, soluble in alcohol.
d30 R: 1.13.
nD20 R: 1.65.
bp: about 221 °C.
mp: about 21 °C.
Use a grade suitable for protein sequencing.

1-Phenylpiperazine. C10H14N2. (M, 162.2). 1130500. [92-54-6]. Slightly viscous, yellow liquid, not miscible with water.
d30 R: 1.07.
nD20 R: 1.588.

White or yellowish crystals, slightly soluble in water, soluble in alcohol.
mp: about 223 °C (instantaneous method).

Phloroglucinol solution. 1064601.
To 1 ml of a 100 g/1 solution of phloroglucinol R in alcohol R, add 9 ml of hydrochloric acid R.
Storage: protected from light.

Phosalone. C12H15ClNO4PS2. (M, 367.8). 1130200. [2310-17-0]. mp: 45 °C to 48 °C.
A suitable certified reference solution (100 ng/µl in iso-octane) may be used.

Phosphomolybdic acid. 12MoO3.H3PO4.xH2O. 1064900. [51429-74-4]. Orange-yellow, fine crystals, freely soluble in water, soluble in alcohol.

Phosphomolybdic acid solution. 1064901.
Dissolve 4 g of phosphomolybdic acid R in water R and dilute to 40 ml with the same solvent. Add cautiously and with cooling 60 ml of sulphuric acid R. Prepare immediately before use.

Phosphomolybdatungstic reagent. 1065000.
Dissolve 100 g of sodium tungstate R and 25 g of sodium molybdate R in 700 ml of water R. Add 100 ml of hydrochloric acid R and 50 ml of phosphoric acid R. Heat the mixture under a reflux condenser in a glass apparatus for 10 h. Add 150 g of lithium sulphate R, 50 ml of water R and a few drops of bromine R. Boil to remove the excess of bromine (15 min), allow to cool, dilute to 1000 ml with water R and filter. The reagent should be yellow in colour. If it acquires a greenish tint, it is unsatisfactory for use but may be regenerated by boiling with a few drops of bromine R. Care must be taken to remove the excess of bromine by boiling.
Storage: at 2 °C to 8 °C.

Phosphomolybdatungstic reagent, dilute. 1065001.
To 1 volume of phosphomolybdatungstic reagent R add 2 volumes of water R.

Phosphoric acid. 1065100. [7664-38-2]. See Concentrated phosphoric acid (0004).

Phosphoric acid, dilute. 1065101.
See Dilute phosphoric acid (0005).

Phosphoric acid, dilute R1. 1065102.
Dilute 93 ml of dilute phosphoric acid R to 1000 ml with water R.

Phosphorous acid. H3PO4. (M, 82.0). 1130600. [13598-36-2]. White or almost white, very hygroscopic and deliquescent crystalline mass; slowly oxidised by oxygen (air) to H3PO4. Unstable, orthorhombic crystals, soluble in water, in alcohol and in a mixture of 3 volumes of ether and 1 volume of alcohol.
d31 R: 1.651.
mp: about 73 °C.

Phosphotungstic acid solution. 1065200.
Heat under a reflux condenser for 3 h, 10 g of sodium tungstate R with 8 ml of phosphoric acid R and 75 ml of water R. Allow to cool and dilute to 100 ml with water R.

A yellow, crystalline powder.
mp: about 55 °C.
Storage: protected from light and air.
Phthalaldehyde reagent. **1065301.**
Dissolve 2.47 g of boric acid R in 75 ml of water R, adjust to pH 10.4 using a 450 g/1 solution of potassium hydroxide R and dilute to 100 ml with water R. Dissolve 1.0 g of phthalaldehyde R in 5 ml of methanol R, add 95 ml of the boric acid solution and 2 ml of trinitro-1,3-dione acid R to the resulting solution and adjust to pH 10.4 with a 450 g/1 solution of potassium hydroxide R.

**Storage:** protected from light; use within 3 days.

Phthalazine. C₈H₆N₂. (M. 130.1). **1065400.** [253-52-1].
Pale yellow crystals, freely soluble in water, soluble in ethanol, in ethyl acetate and in methanol.

mp: 89 °C to 92 °C.

Phthalaldehyde reagent. **1065301.**
Dissolve 2.47 g of boric acid R in 75 ml of water R, adjust to pH 10.4 using a 450 g/1 solution of potassium hydroxide R and dilute to 100 ml with water R. Dissolve 1.0 g of phthalaldehyde R in 5 ml of methanol R, add 95 ml of the boric acid solution and 2 ml of trinitro-1,3-dione acid R to the resulting solution and adjust to pH 10.4 with a 450 g/1 solution of potassium hydroxide R.

**Storage:** protected from light; use within 3 days.

Phthalic anhydride. A white or almost white, crystalline powder, soluble in hot benzene and in alcohol. The product may be found in commerce in the form of the sodium salt: a yellowish-white to pink powder, soluble in water, practically insoluble in alcohol R.

A colourless, oily liquid, odour reminiscent of turpentine, practically insoluble in water, miscible with alcohol.

**Test for sensitivity.** Dissolve 10 mg in 1 ml of concentrated ammonia R and dilute to 100 ml with water R. To 5 ml of the solution add 95 ml of water R, 4 ml of concentrated ammonia R, 50 ml of alcohol R and 0.1 ml of 0.1 M barium chloride. The solution is blue-violet. Add 0.15 ml of 0.1 M sodium edetate. The solution becomes colourless.


A white or almost white, crystalline powder, soluble in hot water and in alcohol.

Phthalic anhydride. C₂₆H₂₆O₈. xH₂O. (M. 637, anhydrous substance). **1065500.** [2411-89-4]. Metalphthalic. 2,2',2'',2'''-o-Cresolphthalic-3,3''-bis(methyleneenitrilo)tetra-acetic acid. (1,3-Dihydro-3-oxo-isobenzofuran-1-ylidene)bis(6-hydroxy-5-methyl-3,1-phenylene)bis(methyleneimino)diacetic acid.

A yellowish-white to brownish powder, practically insoluble in water, soluble in alcohol. The product may be found in commerce in the form of the sodium salt: a yellowish-white to pink powder, soluble in water, practically insoluble in alcohol.

**Test for sensitivity.** Dissolve 10 mg in 1 ml of concentrated ammonia R and dilute to 100 ml with water R. To 5 ml of the solution add 95 ml of water R, 4 ml of concentrated ammonia R, 50 ml of alcohol R and 0.1 ml of 0.1 M barium chloride. The solution is blue-violet. Add 0.15 ml of 0.1 M sodium edetate. The solution becomes colourless.

Phthalic acid. C₈H₆O₄. (M. 166.1). **1066700.** [85-44-9]. Isobenzozuraran-1,3-dione.

**Content:** minimum 99.0 per cent of C₈H₆O₄.

White or almost white flakes.

mp: 130 °C to 132 °C.

**Assay.** Dissolve 2.000 g in 100 ml of water R and boil under a reflux condenser for 30 min. Cool and titrate with 1 M sodium hydroxide solution R as indicator.

1 ml of 1 M sodium hydroxide is equivalent to 74.05 mg of C₈H₆O₄.

Phthalic anhydride solution. **1065701.**
Dissolve 42 g of phthalic anhydride R in 300 ml of anhydrous pyridine R. Allow to stand for 16 h.

**Storage:** protected from light; use within 1 week.

Piccin. C₁₀H₁₀O₄. (M. 298.3). **1130700.** [550-14-3]. 1-(4-β-Isopropyl)glucopyranosyloxyl)-4-phenyltane. p-(Acetylphenyl)phenyl-β-glucopyranoside.

mp: 194 °C to 195 °C.

Picric acid. C₈H₃N₃O₇. (M. 229.1). **1065800.** [88-89-1].

Yellow prisms or plates, soluble in water and in alcohol.

**Storage:** moistened with water R.

**Picric acid solution.** 1065801.
A 10 g/1 solution.

Picric acid solution R1. **1065802.**
Prepare 100 ml of a saturated solution of picric acid R and add 0.25 ml of strong sodium hydroxide solution R.

α-Pinene. C₁₀H₁₆. (M. 136.2). **1130800.** [7785-70-8]. 1R(5R)-2,6,6-Trimethylcyclohexyl 3,1-hept-2-ene.
A liquid not miscible with water.

α-Pinene used in gas chromatography complies with the following additional test.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on *Bitter-orange-flower oil* (1175) using the substance to be examined as the test solution.

The area of the principal peak is not less than 99.0 per cent of the total area of the peaks.

A colourless, oily liquid, odour reminiscent of turpentine, practically insoluble in water, miscible with alcohol.

β-Pinene used in gas chromatography complies with the following additional test.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on *Bitter-orange-flower oil* (1175), using the substance to be examined as the test solution. The area of the principal peak is not less than 99.0 per cent of the total area of the peaks.

Piperazine hydrate. **1065900.** [142-63-2].
See *Piperazine hydrate* (0425).

Piperidine. C₅H₁₁N. (M. 85.2). **1066000.** [110-89-4]. Hexahydropyridine.
A colourless to slightly yellow, alkaline liquid, miscible with water, with alcohol and with light petroleum.

bp: about 106 °C.

Piperitone. C₁₀H₁₆. O. (M. 152.2). **1151200.** [89-81-6]. 6-Isopropyl-3-methyl-cyclohex-2-en-1-one.
Pirimiphos-ethyl. C₁₃H₂₅N₂O₆PS. (M. 333.4). **1130300.** [23505-41-1].

mp: 15 °C to 18 °C.
A suitable certified reference solution (10 ng/μl in cyclohexane) may be used.

Plasma, platelet-poor. **1066100.**
Withdraw 45 ml of human blood into a 50 ml plastic syringe containing 5 ml of a sterile 38 g/1 solution of sodium citrate R. Without delay, centrifuge at 1500 g at 4 °C for 30 min. Remove the upper two-thirds of the supernatant plasma using a plastic syringe and without delay centrifuge at 3500 g at 4 °C for 30 min. Remove the upper two-thirds of the liquid and freeze it rapidly in suitable amounts in plastic tubes at or below −40 °C. Use plastic or silicone-treated equipment.

**Plasma substrate.** **1066200.**
Separate the plasma from human or bovine blood collected into one-ninth its volume of a 38 g/1 solution of sodium citrate R, or into two-sevenths its volume of a solution containing 20 g/1 of disodium hydrogen citrate R and
25 g/l of glucose R. With the former, prepare the substrate on the day of collection of the blood. With the latter, prepare within two days of collection of the blood.

**Storage:** at \(-20\, ^\circ\text{C}\).

**Plasma substrate R1. 1066201.**

Use water-repellent equipment (made from materials such as suitable plastics or suitably silicone-treated glass) for taking and handling blood.

Collect a suitable volume of blood from each of at least five sheep; a 285 ml volume of blood collected into 15 ml of anticoagulant solution is suitable but smaller volumes may be collected, taking the blood, either from a live animal or at the time of slaughter, using a needle attached to a suitable cannula which is long enough to reach the bottom of the collecting vessel. Discarding the first few millilitres and collecting only free-flowing blood, collect the blood in a sufficient quantity of an anticoagulant solution containing 8.7 g of sodium citrate R and 4 mg of aprotinin R per 100 ml of water R to give a final ratio of blood to anticoagulant solution of 19 to 1. During and immediately after collection, swirl the flask gently to ensure mixing but do not allow frothing to occur. When collection is complete, close the flask and cool to \(10\, ^\circ\text{C}\) to \(15\, ^\circ\text{C}\). When cold, pool the contents of all the flasks with the exception of any that show obvious haemolysis or clots and keep the pooled blood at \(10\, ^\circ\text{C}\) to \(15\, ^\circ\text{C}\).

As soon as possible and within 4 h of collection, centrifuge the pooled blood at 1000 to 2000 g for 30 min. Separate the supernatant liquid and centrifuge it at 5000 g for 30 min. (Faster centrifugation, for example 20 000 g for 30 min, may be used if necessary to clarify the plasma, but filtration procedures should not be used.) Separate the supernatant liquid and, without delay, mix thoroughly and distribute the plasma substrate into small stoppered containers in portions sufficient for a complete heparin assay (for example 10 ml to 30 ml). Without delay, rapidly cool to a temperature below \(-70\, ^\circ\text{C}\) (for example by immersing the containers into liquid nitrogen) and store at a temperature below \(-30\, ^\circ\text{C}\).

The plasma is suitable for use as plasma substrate in the assay for heparin if, under the conditions of the assay, it gives a clotting time appropriate to the method of detection used and if it provides reproducible, steep log dose-response curves.

When required for use, thaw a portion of the plasma substrate in a water-bath at \(37\, ^\circ\text{C}\), gently swirling until thawing is complete; once thawed it should be kept at \(10\, ^\circ\text{C}\) to \(20\, ^\circ\text{C}\) and used without delay. The thawed plasma substrate may be lightly centrifuged if necessary; filtration procedures should not be used.

**Plasma substrate R2. 1066202.**

Prepare from human blood containing less than 1 per cent of the normal amount of factor IX. Collect the blood into one-ninth its volume of a 38 g/l solution of sodium citrate R.

**Storage:** in small amounts in plastic tubes at a temperature of \(-30\, ^\circ\text{C}\) or lower.

**Plasma substrate R3. 1066203.**

Prepare from human blood containing less than 1 per cent of the normal amount of factor XI. Collect the blood into one-ninth its volume of a 38 g/l solution of sodium citrate R.

**Storage:** in small amounts in plastic tubes at a temperature of \(-30\, ^\circ\text{C}\) or lower.
Poly(dimethyl)siloxane. 1066800.

Silicone gum rubber (methyl). Organosilicon polymer with the appearance of a semi-liquid, colourless gum.

The intrinsic viscosity, determined as follows is about 115 ml·g⁻¹. Weigh 1.5 g, 1 g and 0.3 g of the substance to be examined to the nearest 0.1 mg, into 100 ml volumetric flasks. Add 40 ml to 50 ml of toluene R, shake until the substance is completely dissolved and dilute to 100.0 ml with the same solvent. Determine the viscosity of each solution by half by diluting with toluene R. Determine the viscosity of these solutions.

\[ c = \text{concentration in grams per 100 ml}, \]
\[ t_1 = \text{flow time of the solution to be examined}, \]
\[ t_2 = \text{flow time of toluene}, \]
\[ \eta_1 = \text{viscosity of the solution to be examined in millipascal seconds}, \]
\[ \eta_2 = \text{viscosity of toluene in millipascal seconds}, \]
\[ d_1 = \text{relative density of the solution to be examined}, \]
\[ d_2 = \text{relative density of toluene}. \]

To obtain the relative densities use the following data.

<table>
<thead>
<tr>
<th>Concentration (g/100 ml)</th>
<th>Relative density (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 0.5</td>
<td>1.000</td>
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<tr>
<td>0.5 - 1.25</td>
<td>1.001</td>
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<tr>
<td>1.25 - 2.20</td>
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<tr>
<td>3.20 - 3.75</td>
<td>1.005</td>
</tr>
<tr>
<td>3.75 - 4.50</td>
<td>1.006</td>
</tr>
</tbody>
</table>

The specific viscosity is obtained from the equation:

\[ \eta_{sp} = \frac{\eta_1 - \eta_2}{\eta_2} = \frac{t_1 d_1}{t_2 d_2} - 1 \]

and the reduced viscosity from:

\[ \eta_{red} = \frac{\eta_{sp}}{c} \]

The intrinsic viscosity (\( \eta_i \)) is obtained by extrapolating the preceding equation to \( c = 0 \). This is done by plotting the curve \( \eta_{sp}/c \) or \( \log \eta_{sp}/c \) as a function of \( c \). Extrapolation to \( c = 0 \) gives \( \eta_i \). The intrinsic viscosity is expressed in millilitres per gram; the value obtained must therefore be multiplied by 100.

The infrared absorption spectrum (2.2.24) obtained by applying the substance, if necessary dispersed in a few drops of carbon tetrachloride R, to a sodium chloride plate, does not show absorption at 3053 cm⁻¹, corresponding to vinyl groups.

**Polyether hydroxylated gel for chromatography.** 1067000. Gel with a small particle size having a hydrophilic surface with hydroxyl groups. It has an exclusion limit for dextran of relative molecular mass 2 × 10⁵ to 2.5 × 10⁶.

**Polyethyleneglycol adipate.** (C₆H₄O₂)ₐ. (M₄, (172.2)ₐ). 1067700. A white or almost white, wax-like mass, practically insoluble in water.

mp: about 43 °C.

**Polyethyleneglycol, base-deactivated.** 1170300. Stationary phase for gas chromatography.

Cross-linked, base-deactivated polyethyleneglycol specially designed for amine analysis.

**Polyethyleneglycol succinate.** (C₈H₁₂O₄)ₐ. (M₈, (144.1)ₐ). 1067800. A white or almost white, crystalline powder, practically insoluble in water.

mp: about 102 °C.

**Polymethacrylate gel, hydroxylated.** 1112300. Stationary phase for size-exclusion chromatography.

Gel based on hydroxylated methacrylic acid polymer.

**Polymethylphenylsiloxane.** 1067900. Stationary phase for gas chromatography.

Contains 50 per cent of methyl groups and 50 per cent of phenyl groups. (Average relative molecular mass 4000).

A very viscous liquid (viscosity about 1300 mPas). A very viscous liquid (viscosity about 1300 mPas).

**Polyoxyethylated castor oil.** 1068200. A light yellow liquid. It becomes clear above 26 °C.

**Polysorbate 20.** 1068300. [9005-65-4].

See Polysorbate 20 (0428).

**Polysorbate 80.** 1068400. [9005-65-4].

See Polysorbate 80 (0426).

**Polystyrene 900-1000.** 1112200. [9003-53-6]. Organic standard used for calibration in gas chromatography.

\[ M_n: 950, \]
\[ M_p/M_n: 1.10. \]

**Potassium bicarbonate.** 1069900. [298-14-6].

See potassium hydrogen carbonate R.

**Potassium bicarbonate solution, saturated methanolic.** 1069901.

See potassium hydrogen carbonate solution, saturated methanolic R.

**Potassium bromate.** KBrO₃. (M₄, 167.0). 1068700. [7758-01-2].

White or almost white granular powder or crystals, soluble in water, slightly soluble in alcohol.
Potassium bromide. 1068800. [7758-02-3]. See Potassium bromide (0184).

Potassium bromide used for infrared absorption spectrophotometry (2.2.24) also complies with the following requirement.

A disc 2 mm thick prepared from the substance previously dried at 250 °C for 1 h, has a substantially flat baseline over the range 4000 cm\(^{-1}\) to 620 cm\(^{-1}\). It exhibits no maxima with absorbance greater than 0.02 above the baseline, except maxima for water at 3440 cm\(^{-1}\) and 1630 cm\(^{-1}\).

Potassium carbonate. K\(_2\)CO\(_3\). (M, 138.2). 1068900. [584-08-7]. Dipotassium carbonate.

A white or almost white, granular powder, hygroscopic, very slightly soluble in alcohol. Sample A: in airtight container.

Storage: in an airtight container.

Potassium chloride. KC\(_\text{I}O_\text{3}\). (M, 122.6). 1069000. [3811-04-9].

A white or almost white powder, granules or crystals, soluble in water. Sample A: airtight container.

Potassium chloride. 1069100. [7447-40-7]. See Potassium chloride (0185).

Potassium chloride used for infrared absorption spectrophotometry (2.2.24) also complies with the following requirement.

A disc 2 mm thick prepared from the substance previously dried at 250 °C for 1 h, has a substantially flat baseline over the range 4000 cm\(^{-1}\) to 620 cm\(^{-1}\). It exhibits no maxima with absorbance greater than 0.02 above the baseline, except maxima for water at 3440 cm\(^{-1}\) and 1630 cm\(^{-1}\).

Potassium chloride, 0.1 M. 1069201.

A solution of potassium chloride R containing the equivalent of 7.46 g of KCl in 1000.0 ml.


Yellow crystals, freely soluble in water, practically insoluble in alcohol. Sample A: 50 g/l solution.

Potassium chromate solution. 1069201.

A 50 g/l solution.

Potassium citrate. 1069300. [6100-05-6]. See Potassium citrate (0400).

Potassium cyanide. KCN. (M, 65.1). 1069400. [151-50-8].

A white or almost white, crystalline powder or white or almost white mass or granules, freely soluble in water, slightly soluble in alcohol.

Potassium cyanide solution. 1069401.

A 100 g/l solution.

Potassium cyanide solution, lead-free. 1069402.

Dissolve 10 g of potassium cyanide R in 90 ml of water R, and add 2 ml of strong hydrogen peroxide solution R diluted 1 to 5. Allow to stand for 24 h, dilute to 100 ml with water R and filter.

The solution complies with the following test: take 10 ml of the solution, add 10 ml of water R and 10 ml of hydrogen sulphide solution R. No colour is evolved even after addition of 5 ml of dilute hydrochloric acid R.


Potassium dichromate used for the calibration of spectrophotometers (2.2.25) contains not less than 99.9 per cent of K\(_2\)Cr\(_2\)O\(_7\), calculated with reference to the substance dried at 130 °C. Orange-red crystals, soluble in water, practically insoluble in alcohol.

Dissolve 1.000 g in water R and dilute to 250.0 ml with the same solvent. To 50.0 ml of this solution add a freshly prepared solution of 4 g of potassium iodide R, 2 g of sodium hydroxide carbonate R and 6 ml of hydrochloric acid R in 100 ml of water R in a 500 ml flask. Stopper the flask and allow to stand protected from light for 5 min. Titrate with 0.1 M sodium thiosulphate, using 1 ml of iodide-free starch solution R as indicator.

1 ml of 0.1 M sodium thiosulphate is equivalent to 4.903 mg of K\(_2\)Cr\(_2\)O\(_7\).

Potassium dichromate solution. 1069501.

A 106 g/l solution.

Potassium dichromate solution R1. 1069502.

A 5 g/l solution.

Potassium dihydrogen phosphate. 1069600. [7778-77-0]. See Potassium dihydrogen phosphate (0920).

Potassium dihydrogen phosphate, 0.2 M. 1069601.

A solution of potassium dihydrogen phosphate R containing the equivalent of 27.22 g of KH\(_2\)PO\(_4\) in 1000.0 ml.


Red crystals, freely soluble in water.

Potassium ferricyanide solution. 1069701.

Wash 5 g of potassium ferricyanide R with a little water R, dissolve and dilute to 100 ml with water R. Prepare immediately before use.


Transparent yellow crystals, freely soluble in water, practically insoluble in alcohol.

Potassium ferrocyanide solution. 1069801.

A 53 g/l solution.


White or almost white, crystalline powder or white or almost white mass or granules, freely soluble in water, slightly soluble in alcohol.

Potassium fluoride solution. 1069901.

Potassium hydrogen carbonate, 0.2 M. 1069900. [298-14-6]. Potassium bicarbonate.

Transparent, colourless crystals, freely soluble in water, practically insoluble in alcohol.

Potassium hydrogen carbonate solution, saturated methanolic. 1069901.

Dissolve 0.1 g of potassium hydrogen carbonate R in 0.4 ml of water R, heating on water-bath. Add 25 ml of methanol R and swirl, keeping the solution on the water-bath until dissolution is complete. Use a freshly prepared solution.
Potassium hydrogen phthalate. \( \text{C}_6\text{H}_5\text{KO}_4 \) (\( M \), 204.2). 1070000. [877-24-7]. Potassium hydrogen benzene-1,2-dicarboxylate.

White or almost white crystals, soluble in water, slightly soluble in alcohol.

Potassium hydrogen phthalate, 0.2 M. 1070001.

A solution of potassium hydrogen phthalate R containing the equivalent of 40.84 g of \( \text{C}_6\text{H}_5\text{KO}_4 \) in 1000.0 ml.

Potassium hydrogen sulphate. \( \text{KHSO}_4 \) (\( M \), 136.2). 1070100. [7646-93-7].

Colourless, transparent, hygroscopic crystals, freely soluble in water giving a strongly acid solution.

Storage: in an airtight container.

Potassium hydrogen tartrate. \( \text{C}_4\text{H}_5\text{KO}_6 \) (\( M \), 188.2). 1070200. [868-14-4]. Potassium hydrogen \((2\text{R},3\text{R})\)-3,3-dihydroxybutane-1,4-dioate.

A white or almost white, crystalline powder or colourless, slightly opaque crystals, slightly soluble in water, soluble in boiling water, practically insoluble in alcohol.

Potassium hydroxide. 1070300. [1310-58-3].

See Potassium hydroxide (0840).

Potassium hydroxide, alcoholic, 2 M. 1070301.

Dissolve 12 g of potassium hydroxide R in 10 ml of water R and dilute to 100 ml with alcohol R.

Potassium hydroxide in alcohol (10 per cent V/V), 0.5 M. 1070302.

Dissolve 28 g of potassium hydroxide R in 100 ml of alcohol R and dilute to 1000 ml with water R.

Potassium hydroxide solution, alcoholic. 1070303.

Dissolve 3 g of potassium hydroxide R in 5 ml of water R and dilute to 100 ml with aldehyde-free alcohol R. Decant the clear solution. The solution should be almost colourless.

Potassium hydroxide solution, alcoholic R1. 1070304.

Dissolve 6.6 g of potassium hydroxide R in 50 ml of water R and dilute to 1000 ml with ethanol R.

Potassium iodate. \( \text{KIO}_3 \) (\( M \), 214.0). 1070400. [7758-05-6].

A white or almost white, crystalline powder, soluble in water.

Potassium iodide. 1070500. [7681-11-0].

See Potassium iodide (0186).

Potassium iodide and starch solution. 1070501.

Dissolve 0.75 g of potassium iodide R in 100 ml of water R. Heat to boiling and add whilst stirring a solution of 0.5 g of soluble starch R in 35 ml of water R. Boil for 2 min and allow to cool.

Test for sensitivity. A mixture of 15 ml of the potassium iodide and starch solution, 0.05 ml of glacial acetic acid R and 0.3 ml of iodine solution R2 is blue.

Potassium iodide solution. 1070502.

A 166 g/l solution.

Potassium iodide solution, iodinated. 1070503.

Dissolve 2 g of iodine R and 4 g of potassium iodide R in 10 ml of water R. When solution is complete dilute to 100 ml with water R.

Potassium iodide solution, iodinated R1. 1070505.

Dissolve 500 mg of iodine R and 1.5 g of potassium iodide R in water R and dilute to 25 ml with the same solvent.

Potassium iodide solution, saturated. 1070504.

A saturated solution of potassium iodide R in carbon dioxide-free water R. Make sure the solution remains saturated as indicated by the presence of undissolved crystals.

Test by adding to 0.5 ml of the saturated potassium iodide solution 30 ml of a mixture of 2 volumes of chloroform R and 3 volumes of glacial acetic acid R, as well as 0.1 ml of starch solution R. Any blue colour formed should be discharged by the addition of 0.05 ml of 0.1 M sodium thiosulphate.

Storage: protected from light.

Potassium iodobismuthate solution. 1070600.

To 0.85 g of bismuth subnitrate R add 40 ml of water R, 10 ml of glacial acetic acid R and 20 ml of a 400 g/l solution of potassium iodide R.

Potassium iodobismuthate solution R1. 1070601.

Dissolve 100 g of tartaric acid R in 400 ml of water R and add 8.5 g of bismuth subnitrate R. Shake for 1 h, add 200 ml of a 400 g/l solution of potassium iodide R and shake well. Allow to stand for 24 h and filter.

Storage: protected from light.

Potassium iodobismuthate solution R2. 1070602.

Stock solution. Suspend 1.7 g of bismuth subnitrate R and 20 g of tartaric acid R in 400 ml of water R. To the suspension add 40 ml of a 400 g/l solution of potassium iodide R and stir for 1 h. Filter. The solution may be kept for several days in brown bottles.

Spray solution. Mix immediately before use 5 ml of the stock solution with 15 ml of water R.

Potassium iodobismuthate solution R3. 1070604.

Dissolve 0.17 g of bismuth subnitrate R in a mixture of 2 ml of glacial acetic acid R and 18 ml of water R. Add 4 g of potassium iodide R, 1 g of iodine R and dilute to 100 ml with dilute sulphuric acid R.

Potassium iodobismuthate solution R4. 1070605.

Dissolve 1.7 g of bismuth subnitrate R in 20 ml of glacial acetic acid R. Add 80 ml of distilled water R, 100 ml of a 400 g/l solution of potassium iodide R, 200 ml of glacial acetic acid R and dilute to 1000 ml with distilled water R. Mix 2 volumes of this solution with 1 volume of a 200 g/l solution of barium chloride R.

Potassium iodobismuthate solution R5. 1070606.

To 0.85 g of bismuth subnitrate R add 10 ml of glacial acetic acid R and gently heat until completely dissolved. Add 40 ml of water R and allow to cool. To 5 ml of this solution, add 5 ml of a 400 g/l solution of potassium iodide R, 20 ml of glacial acetic acid R and 70 ml of water R.

Potassium iodobismuthate solution, dilute. 1070603.

Dissolve 100 g of tartaric acid R in 500 ml of water R and add 50 ml of potassium iodobismuthate solution R1.

Storage: protected from light.

Potassium nitrate. \( \text{KNO}_3 \) (\( M \), 101.1). 1070700. [7757-79-1].

Colourless crystals, very soluble in water.

Potassium nitrate solution. 1070701.

A solution of potassium nitrate R in water R. Make sure the solution remains saturated as indicated by the presence of undissolved crystals.

Test by adding to 0.5 ml of the saturated potassium nitrate solution 30 ml of a mixture of 2 volumes of chloroform R and 3 volumes of glacial acetic acid R, as well as 0.1 ml of starch solution R. Any blue colour formed should be discharged by the addition of 0.05 ml of 0.1 M sodium thiosulphate.

Storage: protected from light.
Potassium ferriperiodate solution. 1070801.
Dissolve 1 g of potassium periodate R in 5 ml of a freshly prepared 120 g/l solution of potassium hydroxide R. Add 20 ml of water R and 1.5 ml of ferric chloride solution R1. Dilute to 50 ml with a freshly prepared 120 g/l solution of potassium hydroxide R.

Potassium permanganate. 1070900. [7722-64-7].
See Potassium permanganate (0121).

Potassium permanganate and phosphoric acid solution. 1070901.
Dissolve 3 g of potassium permanganate R in a mixture of 15 ml of phosphoric acid R and 70 ml of water R. Dilute to 100 ml with water R.

Potassium permanganate solution. 1070902.
A 30 g/l solution.

Potassium perhenate. KReO₄. (M₁ 289.3). 1071000. [10466-65-6].
A white or almost white, crystalline powder, soluble in water, slightly soluble in alcohol, in methanol and in propylene glycol.

Colourless crystals or a white or almost white, crystalline powder, sparingly soluble in water, practically insoluble in alcohol. Aqueous solutions decompose at room temperature and more rapidly on warming.

Potassium plumbite solution. 1071200.
Dissolve 1.7 g of lead acetate R, 3.4 g of potassium citrate R and 50 g of potassium hydroxide R in water R and dilute to 100 ml with the same solvent.

White or almost white, crystals or crystalline powder, sparingly soluble in water.

Potassium pyroantimonate solution. 1071301.
Dissolve 2 g of potassium pyroantimonate R in 95 ml of hot water R. Cool quickly and add a solution containing 2.5 g of potassium hydroxide R in 50 ml of water R and 1 ml of dilute sodium hydroxide solution R. Allow to stand for 24 h, filter and dilute to 150 ml with water R.

White or almost white, granular powder or crystals, very soluble in water, very slightly soluble in alcohol.

Potassium tetraiodomercurate solution. 1071500.
Dissolve 1.35 g of mercuric chloride R in 50 ml of water R. Add 5 g of potassium iodide R and dilute to 100 ml with water R.

Potassium tetraiodomercurate solution, alkaline. 1071600.
Dissolve 11 g of potassium iodide R and 15 g of mercuric iodide R in water R and dilute to 100 ml with the same solvent. Immediately before use, mix 1 volume of this solution with an equal volume of a 250 g/l solution of sodium hydroxide R.

Potassium tetroxalate. C₃H₅KO₃.2H₂O. (M₅ 254.2). 1071700. [6100-20-5].
A white or almost white, crystalline powder, sparingly soluble in water, soluble in boiling water, slightly soluble in alcohol.

Potassium thiocyanate. KSCN. (M₆ 97.2). 1071800. [333-20-0].
Colourless crystals, deliquescent, very soluble in water and in alcohol.
Storage: in an airtight container.

Potassium thiocyanate solution. 1071801.
A 97 g/l solution.

Povidone. 1068500. [9003-39-8].
See Povidone (0685).

Procaine hydrochloride. 1109400.
See Procaine hydrochloride (0050).

White or almost white, finely crystallised powder, freely soluble in water and in mineral acids, soluble in alcohol.
Content: minimum 99.0 per cent of C₅H₉NO₂.
\[\text{minimum } 99.0\% \] per cent of C₅H₉NO₂.

A clear colourless liquid, miscible with water and with alcohol.

Distillation range (2.2.11). Not less than 95 per cent distils between 96 °C and 99 °C.

2-Propanol. C₃H₇O. (M₉ 60.1). 1072100. [67-63-0]. Isopropyl alcohol.
A clear, colourless, flammable liquid, miscible with water and with alcohol.

\[\text{distilled water: } 0.802 \text{ to } 0.806\]
\[\text{bp: } 97.2 \pm 0.2 ^\circ C\]

2-Propanol R1. 1072101.
Complies with the requirements prescribed for 2-propanol R and with the following requirements:
\[\text{minimum } 93.7\% \] per cent of C₃H₇O.
\[\text{water (2.5.12): maximum } 0.05\% \] per cent, determined on 10 g.

Propetamphos. C₁₀H₂₀NO₄PS. (M₁₀ 281.3). 1130900. [31218-83-4].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Propidium iodide. C₁₆H₁₇I₃N₆. (M₁₁ 668.4). 1154200. [25535-16-4]. 3,8-Diamino-5-[3(diethylmethylammonio)propyl]-6-phenylphenanthridinium diiodide.
Dark red solid.
**4.1.1. Reagents**

**Propionaldehyde.** C₃H₆O. (M, 58.1). 1072300. [123-38-6].
Propanal.
A liquid freely soluble in water, miscible with alcohol.
d₅⁰: about 0.81.
ρ⁰: about 1.035.
bp: about 49 °C.
mp: about –81 °C.

**Propionic acid.** C₄H₆O₂. (M, 74.1). 1072400. [79-09-4].
An oily liquid, soluble in alcohol, miscible with water.
d₅⁰: about 0.993.
ρ⁰: about 1.387.
bp: about 141 °C.
mp: about –21 °C.

**Propionic anhydride.** C₄H₆O₃. (M, 130.1). 1072500. [123-62-6].
A clear, colourless liquid, soluble in alcohol.
d₅⁰: about 1.01.
bp: about 167 °C.

**Propionic anhydride reagent.** 1072501.
Dissolve 1 g of toluenesulphonic acid R in 30 ml of glacial acetic acid R, add 5 ml of propionic anhydride R and allow to stand for at least 15 min before use.

**Propyl acetate.** C₅H₁₀O₂. (M, 102.1). 1072600. [109-60-4].
d₅⁰: about 0.888.
bp: about 102 °C.
mp: about –95 °C.

**Propyl parahydroxybenzoate.** 1072700. [94-13-3].
See Propyl parahydroxybenzoate (0431).

**D-Prolyl-l-phenylalanine 3-nitroanilide dihydrochloride.** C₃H₅Cl₆N₆O₇. (M, 612). 1072800.

**Propylene glycol.** 1072900. [57-55-6].
See Propylene glycol (0430).

**Propylene oxide.** C₃H₆O. (M, 58.1). 1073000. [110-86-1].
A colourless liquid, very soluble in water and in alcohol.
bp: about 115 °C.
mp: about 23 °C.

**Pyridine.** C₅H₄N. (M, 79.1). 1073200. [110-86-1].
A clear, colourless liquid, hygroscopic, miscible with water and with alcohol.
bp: about 115 °C.

**Pyridine, anhydrous.** 1073300. [110-86-1].
Dry pyridine R over anhydrous sodium carbonate R. Filter and distil.

**Pyridinium hydrobromide perbromide.** C₅H₄Br₃N. (M, 319.8). 1166100. [39416-48-3]. Pyridinium tribromide(1-).

**Pyridylazonaphthol.** 1073400. [504-29-0].
2-Aminopyridine.
Large crystals soluble in water and in alcohol.
bp: about 210 °C.
mp: about 58 °C.

**Pyridylazonaphthol solution.** 1073501.
A 1 g/l solution in ethanol R.

**Pyridylazonaphthol solution.** 1073600.
A 1 g/l solution in ethanol R.

**Test for sensitivity.** To 50 ml of water R add 10 ml of acetate buffer solution pH 4.4 R, 0.10 ml of 0.02 M sodium edetate and 0.25 ml of the pyridylazonaphthol solution. After addition of 0.15 ml of a 5 g/l solution of copper sulphate R, the colour changes from light yellow to violet.

**Pyridylazonaphthol solution.** 1073700.
A 1 g/l solution in ethanol R.

**Pyridylazonaphthol solution.** 1073800.
A 1 g/l solution in ethanol R.

**Pyridylazonaphthol solution.** 1073900.
A 1 g/l solution in ethanol R.

**Pyridylazonaphthol solution.** 1074000.
A 1 g/l solution in ethanol R.

**Pyridylazonaphthol solution.** 1074100.
A 1 g/l solution in ethanol R.

**4-(2-Pyridyldiazol)resorcinol monosodium salt.** C₁₁H₈N₃NaO₂. H₂O. (M, 255.2). 1131500. [16593-81-0].
Orange crystalline powder.

**Pyrocatechol.** C₆H₆O₂. (M, 110.1). 1073600. [120-80-9].
Benzene-1,2-diol.

**Putrescine.** C₁₂H₁₆N₂. (M, 185.8). 1133700. [110-60-1].
1,4-Butanediol. Tetramethylenediol.

**Pulegone.** C₁₀H₁₆O. (M, 152.2). 1073100. [75-56-9].
(+)-(−)-2-Isopropylidene-5-methylcyclohexanone.

**Putrescine.** C₁₂H₁₆N₂. (M, 185.8). 1133700. [110-60-1].
1,4-Butanediol. Tetramethylenediol.

**Pyrogallol.** C₆H₆O₃. (M, 94.1). 1073300. [120-80-9].
Benzene-1,2-diol.

**Pyrogallol.** C₆H₆O₃. (M, 94.1). 1073300. [120-80-9].
Benzene-1,2-diol.

**Pyrogallol.** C₆H₆O₃. (M, 94.1). 1073300. [120-80-9].
Benzene-1,2-diol.

**Pyrogallol.** C₆H₆O₃. (M, 94.1). 1073300. [120-80-9].
Benzene-1,2-diol.
**Pyrogallol.** C₇H₅O₅. (M, 126.1). 1073700. [87-66-1]. Benzene-1,2,3-triol.

White or almost white crystals, becoming brownish on exposure to air and light, very soluble in water and in alcohol, slightly soluble in carbon disulphide. On exposure to air, aqueous solutions, and more rapidly alkaline solutions, become brown owing to the absorption of oxygen.

mp: about 131 °C.

Storage: protected from light.

**Pyrogallol solution, alkaline.** 1073701.

Dissolve 0.5 g of pyrogallol R in 2 ml of carbon dioxide-free water R. Dissolve 12 g of potassium hydroxide R in 8 ml of carbon dioxide-free water R. Mix the two solutions immediately before use.

**Pyryldione.** C₇H₅N. (M, 71.1). 1165000. [123-75-1].

Content: minimum 99 per cent of C₇H₅N.

bp: 87 °C to 88 °C.

2-Pyryldione. C₇H₅NO. (M, 85.1). 1138000. [616-45-5].

Pyryldin-2-one.

Liquid above 25 °C, miscible with water, with ethanol and with ethyl acetate.

d₂₀°: 1.116.

**Pyruvic acid.** C₃H₄O₃. (M, 88.1). 1109300. [127-17-3].

2-Oxopropanoic acid.

A yellowish liquid, miscible with water and with ethanol.

d₂₀°: about 1.267.

π₂₀°: about 1.413.

bp: about 165 °C.

**Quercetin dihydrate.** C₁₇H₁₄O₇.2H₂O. (M, 338.2). 1138100.

2-(3,4-Dihydroxyphenyl)-3,5,7-trihydroxy-4H-1-benzopyran-4-one.

Yellow crystals or yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

Water (2.5.12): maximum 12.0 per cent, determined on 0.100 g.

Assay. Examine by liquid chromatography (2.2.99) as prescribed in the monograph on Ginkgo leaf (1828).

The content is not less than 90 per cent (anhydrous substance) calculated by the normalisation procedure.

Storage: protected from light.

**Quercetin.** C₁₇H₁₄O₇. (M, 448.4). 1138200. [522-12-3]. Quercetin 3-4-rhamnopyranoside.

3-[6-Deoxy-α-L-rhamnopyranosyl]oxyl-2-[3,4-dihydroxyphenyl]-5,7-dihydroxy-4H-1-benzopyran-4-one.

Quercetoside.

Yellow crystals, practically insoluble in cold water, soluble in alcohol.

mp: 176 °C to 179 °C.

Chromatography. Examine as prescribed in the monograph on Goldnrod (1892) applying 20 µl of the solution. After spraying, the chromatogram shows a yellowish-brown fluorescent zone with an Rf of about 0.6.

Storage: at a temperature of 2 °C to 8 °C.

**Quinaldine red.** C₁₄H₁₃N₂. (M, 430.3). 1073800. [117-92-0].

2-[2-[4-(Dimethylamino)phenyl][ethenyl]-1-ethylquinolinium iodide.

Dark bluish-black powder, sparingly soluble in water, freely soluble in alcohol.

Dissolve 0.1 g of quinaldine red R in methanol R and dilute to 100 ml with the same solvent.

Colour change: pH 1.4 (colourless) to pH 3.2 (red).

**Quinhydrone.** C₁₇H₁₈N₂O₂. (M, 218.2). 1073900. [106-34-3].

Equimolecular compound of 1,4-benzoquinone and hydroquinone.

Dark green, lustrous crystals or a crystalline powder, slightly soluble in water, sparingly soluble in hot water, soluble in alcohol and in concentrated ammonia.

mp: about 170 °C.

**Quinidine.** C₂₀H₂₄N₂O₂. (M, 324.4). 1074000. [56-54-2].

(S)-6-Methoxyquinol-4-yl)[(2R,4S,5R)-5-vinylquinuclidin-2-yl]methanol.

White or almost white crystals, very slightly soluble in water, sparingly soluble in alcohol, slightly soluble in methanol.

[α]D²⁰: about +260, determined on a 10 g/1 solution in ethanol R.

mp: about 172 °C.

Storage: protected from light.

**Quinidine sulphate.** 1109500. [6591-63-5].

See Quinidine sulphate (0017).

**Quinine.** C₂₀H₂₃N₂O₉. (M, 324.4). 1074100. [130-95-0].

(R)-6-Methoxyquinol-4-yl)[(2S,4S,5R)-5-vinylquinuclidin-2-yl]methanol.

A white or almost white, microcrystalline powder, very slightly soluble in water, slightly soluble in boiling water, very soluble in ethanol.

[α]D²⁰: about –167, determined on a 10 g/1 solution in ethanol R.

mp: about 175 °C.

Storage: protected from light.

**Quinine hydrochloride.** 1074200. [6119-47-7].

See Quinine hydrochloride (0018).

**Quinine sulphate.** 1074300. [6119-70-6].

See Quinine sulphate (0019).

**Rabbit erythrocyte suspension.** 1074500.

Prepare a 1.6 per cent V/V suspension of rabbit erythrocytes as follows: defibrinate 15 ml of freshly drawn rabbit blood by shaking with glass beads, centrifuge at 2000 g for 10 min and wash the erythrocytes with three quantities, each of 30 ml, of a 9 g/l solution of sodium chloride R. Dilute 1.6 ml of the suspension of erythrocytes to 100 ml with a mixture of 1 volume of phosphate buffer solution pH 7.2 R and 9 volumes of a 9 g/l solution of sodium chloride R.

**Raclopride tartrate.** C₁₉H₂₁ClN₂O₆. (M, 497.3). 1144700. [98185-20-7]. Raclopride L-tartrate.

A white or almost white solid, sensitive to light, soluble in water.

[α]D²⁰: + 0.3, determined on a 3 g/l solution.

mp: about 141 °C.

**Rapeseed oil.** 1074600.

See Rapeseed oil, refined (1369).

**Reducing mixture.** 1074700.

Grind the substances added in the following order to obtain a homogeneous mixture: 20 mg of potassium bromide R, 0.5 g of hydrazine sulphate R and 5 g of sodium chloride R.
Resin for reversed-phase ion chromatography. 1131100.
A neutral, macroporous, high specific surface area with a non-polar character resin consisting of polymer lattice of polystyrene cross-linked with divinylbenzene.

Resin, weak cationic. 1096000.
See weak cationic resin R.

Resorcinol. 1074800. [108-46-3].
See Resorcinol (0290).

Resorcinol reagent. 1074810.
To 80 ml of hydrochloric acid R1 add 10 ml of a 20 g/l solution of resorcinol R and 0.25 ml of a 25 g/l solution of copper sulphate R and dilute to 100.0 ml with water R. Prepare the solution at least 4 h before use.

Storage: at 2 °C to 8 °C for 1 week.

Rhamnose. C_{10}H_{16}O_{5}·H_{2}O. (M, 182.2). 1074900. [6155-35-7]. L-4-Rhamnose. 6-Deoxy-l-mannose.
A white or almost white, crystalline powder, freely soluble in water.

[ŋ]_{D}^{20} : + 7.8 to + 8.3, determined on a 50 g/l solution in water R containing about 0.05 per cent of NH_{3}.

A yellowish-grey, crystalline powder, soluble in alcohol and in methanol.

Chromatography. Examine as prescribed in the monograph on Rhubarb (0291); the chromatogram shows only one principal spot.

Rhodamine 6 G. C_{22}H_{20}ClN_{2}O_{3}. (M, 479.0). 1153300. [899-38-8].
Colour Index No. 45160. 9-[2-(Ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthenyl chloride.
Brownish-red powder.

Rhodamine B. C_{22}H_{20}ClN_{2}O_{3}. (M, 479.0). 1075100. [81-88-9].
Schultz No. 864.
Colour Index No. 45170. 9-[2-(Carboxybenzoyl)-6-(diethylamino)-3Hxanthen-3-yliden]diethylammonium chloride.
Green crystals or reddish-violet powder, very soluble in water and in alcohol.

Ribose. C_{5}H_{10}O_{5}. (M, 150.1). 1109600. [50-46-9]. D-Ribose.
Soluble in water, slightly soluble in alcohol.
mp: 88 °C to 92 °C.

Ricinoleic acid. C_{18}H_{32}O_{3}. (M, 298.5). 1101000. [141-22-0].
12-Hydroxyoleic acid.
A yellow or yellowish-brown viscous liquid, consisting of a mixture of fatty acids obtained by the hydrolysis of castor oil, practically insoluble in water, very soluble in ethanol.

δ_{D}^{20} : about 0.942.

n_{D}^{20} : about 1.472.

mp: about 285 °C, with decomposition.

Rosmarinic acid. C_{18}H_{18}O_{8}. (M, 360.3). 1138300. [20283-92-5].
mp: 170 °C to 174 °C.

Ruthenium red. [(NH_{3})_{5}RuORu(NH_{3})_{4}ORu(NH_{3})_{5}]Cl_{6}·4H_{2}O. (M, 858). 1075200. [11103-72-3].
A brownish-red powder, soluble in water.

Rutin. C_{34}H_{38}O_{15}·3H_{2}O. (M, 665). 1075300. [153-18-4].
Rutoside. 3-(4-Deoxy-α-L-mannopyranosyl)-(1→6)-β-D-glucopyranosylxylo)-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4Hchromen-4-one.
A yellow, crystalline powder, darkening in light, very slightly soluble in water, soluble in about 400 parts of boiling water, slightly soluble in alcohol, soluble in solutions of the alkali hydroxides and in ammonia.
mp: about 210 °C, with decomposition.

A solution in alcohol R shows two absorption maxima (2.2.25), at 259 nm and 362 nm.

Storage: protected from light.

Sabine. C_{9}H_{16}. (M, 136.2). 1109700. [3387-41-5].
Thuj-4(10)-ene. 4-Methylene-1-isopropylbicyclo[3.1.0]hexane.
A colourless, oily liquid.

Sabine used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Bitter-orange-flower oil (1175), using the substance to be examined as the test solution.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Saccharin sodium. 1131400. [128-44-9].
See Saccharin sodium (0787).

Safrole. C_{10}H_{10}O_{2}. (M, 162.2). 1131200. [94-59-7]. 5-(Prop-2-enyl)-1,3-benzodioxole. 4-Allyl-1,2(methylenedioxy)benzene.
A colourless, slightly yellow, oily liquid, with the odour of sassafras, insoluble in water, very soluble in alcohol, miscible with hexane.

δ_{D}^{20} : 1.095 to 1.096.

n_{D}^{20} : 1.537 to 1.538.

bp: 232 °C to 234 °C.

Freezing point: about 11 °C.

Safrole used in gas chromatography complies with the following additional test.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Cinnamon bark oil, Ceylon (1501).

The content is not less than 96.0 per cent, calculated by the normalisation procedure.

Salicylaldehyde. C_{7}H_{6}O_{2}. (M, 122.1). 1131300. [90-02-8].
2-Hydroxybenzaldehyde.
A clear, colourless, oily liquid.

δ_{D}^{20} : about 1.167.

n_{D}^{20} : about 1.574.

bp: about 196 °C.

mp: about –7 °C.
Salicylaldehyde azine. \( \text{C}_9\text{H}_9\text{N}_2\text{O}_2 \) (M, 240.3). \text{1075500.} [959-36-4]. 2,2'-Azinodimethyldiphenol.

Dissolve 0.30 g of **hidrazine sulphate R** in 5 ml of water \( R \), add 1 ml of glacial acetic acid \( R \) and 2 ml of a freshly prepared 20 per cent \( V/V \) solution of **salicylaldehyde R** in 2-propanol \( R \). Mix, allow to stand until a yellow precipitate is formed. Shake with two quantities, each of 15 ml, of **methylene chloride R**. Combine the organic layers and dry over anhydrous sodium sulphate \( R \). Decant or filter the solution and evaporate to dryness. Recrystallise from a mixture of 40 volumes of **methanol R** and 60 volumes of **toluene R** with cooling. Dry the crystals in vacto. mp: about 213 °C.

**Chromatography.** Examine as prescribed in the test for hydrazine in the monograph on **Povidone (0685)**; the chromatogram shows only one principal spot.

**Salicylic acid.** \text{1075600.} [69-72-7]. See Salicylic acid (0366).

**Sand.** \text{1075800.}

White or slightly greyish grains of silica with a particle size between 150 µm and 300 µm.

**Santonin.** \( \text{C}_{20}\text{H}_{16}\text{O}_5 \) (M, 246.3). \text{1122000.} [481-06-1]. (-)-\text{Santonin.} 3,5,9-Trimethyl-3a,5,5a,9b-tetrahydro-3H,4H-naphth[1,2]-furan-2,8-dione.

Colourless, shiny crystals colouring yellow in light, very slightly soluble in water, freely soluble in hot ethanol, sparingly soluble in ethanol.

\[ \alpha \text{D}^{19} = -173 \text{ in ethanol.} \]

mp: 174 °C to 176 °C.

**Chromatography.** Examine as prescribed in identification test C in the monograph on **Arnica flower (1391)**, the chromatogram obtained with 10 µl of the solution shows a quenching zone with an \( R_f \) value of about 0.5. Spray with anisaldehyde solution \( R \) and examine while heating at 105 °C for 5 min to 10 min. In daylight the quenching zone is at first a yellow zone that quickly changes to a violet-red zone.

**Sclareol.** \( \text{C}_{20}\text{H}_{16}\text{O}_5 \) (M, 308.5). \text{1133900.} [515-03-7]. (1R,2R,4aS,5aS)-1-[3(R)-3-Hydroxy-3-methylpent-4-enyl]-2,5,8a-tetramethyldecahyronaphthalen-2-ol.

Odourless crystals.

\[ \alpha \text{D}^{25} = 6.7, \text{ in solution in ethanol.} \]

bp\[10 \text{ mm.}] = 218 °C to 220 °C.

mp: 96 °C to 98 °C.

**Sclareol used in the chromatographic profile test in the monograph on Clary sage oil (1850) complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on **Clary sage oil (1850)**.

The content of sclareol is not less than 97 per cent, calculated by the normalisation procedure.

**Scopoletin.** \( \text{C}_{13}\text{H}_{10}\text{O}_5 \) (M, 192.2). \text{1158700.} [92-61-5].

7-Hydroxy-6-methoxy-2H-1-benzopyran-2-one.

7-Hydroxy-6-methoxycoumarin.

Faintly beigé, fine crystals.

mp: 202 °C to 208 °C.

**SDS-PAGE running buffer.** \text{1114900.}

Dissolve 151.4 g of **tris(hydroxymethyl)aminomethane R**, 721.0 g of **glycine R** and 50.0 g of **sodium lauryl sulphate R** in water \( R \) and dilute to 5000 ml with the same solvent.

Immediately before use, dilute to 10 times its volume with water \( R \) and mix. Measure the pH (2.2.3) of the diluted solution. The pH is between 8.1 and 8.8.

**SDS-PAGE sample buffer (concentrated).** \text{1115000.}

Dissolve 1.89 g of **tris(hydroxymethyl)aminomethane R**, 5.0 g of **sodium lauryl sulphate R** and 50 mg of **bromophenol blue R** in water \( R \). Add 25.0 ml of **glycerol R** and dilute to 100 ml with water \( R \). Adjust the pH to 6.8 with **hydrochloric acid R**, and dilute to 125 ml with water \( R \).

**SDS-PAGE sample buffer for reducing conditions (concentrated).** \text{1122100.}

Dissolve 3.78 g of **tris(hydroxymethyl)aminomethane R**, 10.0 g of **sodium dodecyl sulphate R** and 100 mg of **bromophenol blue R** in water \( R \). Add 50.0 ml of **glycerol R** and dilute to 200 ml with water \( R \). Add 25.0 ml of **2-mercaptoethanol R**. Adjust to pH 6.8 (2.2.3) with **hydrochloric acid R**, and dilute to 250.0 ml with water \( R \).

Alternatively, dithiothreitol may be used as reducing agent instead of 2-mercaptoethanol. In this case prepare the sample buffer as follows: dissolve 3.78 g of **tris(hydroxymethyl)aminomethane R**, 10.0 g of **sodium dodecyl sulphate R** and 100 mg of **bromophenol blue R** in water \( R \). Add 50.0 ml of **glycerol R** and dilute to 200 ml with water \( R \). Adjust to pH 6.8 (2.2.3) with **hydrochloric acid R**, and dilute to 250.0 ml with water \( R \). Immediately before use, add dithiothreitol \( R \) to a final concentration of 100 mM.

**Selenious acid.** \( \text{H}_2\text{SeO}_3 \) (M, 129.0). \text{1100200.} [7783-00-8].

Diluenced crystals, freely soluble in water.

**Storage:** in an airtight container.

**Selenium.** Se. (M, 79.0). \text{1075900.} [7782-49-2].

A brown-red to black powder or granules, practically insoluble in water and in alcohol, soluble in nitric acid.

mp: about 220 °C.

**Serine.** \text{1076000.} [56-45-1].

See Serine (0788).

**Silicic acid.** \text{1001100.} [131-48-6].

See N-acetylglycaminic acid R.

**Silibinin.** \( \text{C}_{20}\text{H}_{24}\text{O}_4 \) (M, 482.4). \text{1151400.} [22888-70-6].

Silybin. (2R,3R)-3,5,7-Trihydroxy-2-(2R,3R)-3(4-hydroxy-3-methoxyphenyl)-2-(hydroxymethyl)-2,3-dihydro-1,4-benzodioxin-6-yl)-2,3-dihydro-4H-1-benzopyran-4-one.

White to yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

**Silibinin used in the assay of Milk-thistle fruit (1860) complies with the following requirement.**

**Assay.** Examine by liquid chromatography (2.2.29) as prescribed in the monograph on **Milk-thistle fruit (1860)**.

**Test solution.** Dissolve 5.0 mg of silibinin, dried in vacuo, in methanol \( R \) and dilute to 50.0 ml with the same solvent.

The silibinin A and silibinin B content is not less than 95.0 per cent, calculated by the normalisation procedure.

**Silica gel \( \pi \)-acceptor/\( \pi \)-donor for chiral separations.** \text{1160100.}

A very finely divided silica gel for chromatography consisting of spherical particles to which 1-(3,5-dinitrobenzamido)-1,2,3,4-tetrahydrophenantrene has been covalently bound, showing both \( \pi \)-electron acceptor and \( \pi \)-electron donor characteristics. The particle size and the configuration are indicated after the name of the reagent in the tests where it is used.
Silica gel AGP for chiral chromatography. 1148700.
A very finely divided silica gel for chromatography consisting of spherical particles coated with α-l-acid glycoprotein. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel, anhydrous. 1076100. [112926-00-8].
Partly dehydrated polymerised, amorphous silicic acid, absorbing at 20 °C about 30 per cent of its mass of water. Practically insoluble in water, partly soluble in solutions of sodium hydroxide. It contains a suitable indicator for detection of the humidity status, for which the colour change from the hydrated to anhydrous form is given on the label.

Silica gel BC for chiral chromatography. 1161300.
A very finely divided silica gel for chromatography (5 µm) coated with β-cyclodextrin. Higher selectivity may be obtained when cyclodextrin has been derivatized with propylene oxide.

Silica gel for chromatography. 1076900.
A very finely divided (3 µm-10 µm) silica gel. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, alkyl-bonded for use with highly aqueous mobile phases. 1160200.
A very finely divided silica gel with bonded alkyl groups suitable for use with highly aqueous mobile phases.

Silica gel for chromatography, amidohexadecylsilyl. 1170400.
A very finely divided silica gel with a fine particle size, chemically modified at the surface by the bonding of amidohexadecylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, aminohexadecylsilyl. 1138400.
A very finely divided (3-10 µm) silica gel with a fine particle size chemically modified at the surface by the bonding of aminohexadecylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, dimethyloctadecylsilyl. 1115100.
A very finely divided silica gel (3 µm-10 µm), chemically modified at the surface by the bonding of dimethyloctadecylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, cyanosilyl. 1109900.
A very finely divided silica gel chemically modified at the surface by the bonding of cyanosilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, di-isobutyloctadecylsilyl. 1110000.
A very finely divided silica gel chemically modified at the surface by the bonding of di-isobutyloctadecylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, diisopropylcyanopropylsilyl. 1168100.
A very finely divided silica gel chemically modified at the surface by the bonding of diisopropylcyanopropylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, dipropylcyanopropylsilyl. 1168100.
A very finely divided silica gel chemically modified at the surface by the bonding of diisopropylcyanopropylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel AGP for chiral chromatography. 1148700.
A very finely divided silica gel for chromatography consisting of spherical particles coated with α-l-acid glycoprotein. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, butylsilyl. 1076200.
A very finely divided silica gel (3 µm-10 µm), chemically modified at the surface by the bonding of butylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Spheroidal silica: 30 nm.
Specific surface area: 80 m²/g.

Silica gel for chromatography, butylsilyl, end-capped. 1170500.
A very finely divided silica (3-10 µm), chemically modified at the surface by the bonding of butylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol (96 per cent).

Silica gel for chromatography, amylose derivative of. 1109800.
A very finely divided (10 µm) silica gel, chemically modified at the surface by the bonding of an amylose derivative. The particle size is indicated after the name of the reagent in the test where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, amylose derivative of. 1109800.
A very finely divided (10 µm) silica gel, chemically modified at the surface by the bonding of an amylose derivative. The particle size is indicated after the name of the reagent in the test where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.
Silica gel for chromatography, diol. 1110000.
Spherical silica particles to which dihydroxypropyl groups are bonded. Pore size 10 nm.

Silica gel for chromatography, hexadecylamidlysilyl. 1162500.
A very finely divided (5 µm) silica gel, chemically modified at the surface by the introduction of hexadecylcarboxamidopropylmethylsilyl groups.

Silica gel for chromatography, hexylsilyl. 1077100.
A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of hexylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, human albumin coated. 1138500.
A very finely divided (3 µm to 10 µm) silica gel with a pore size of 10 nm and a carbon loading of 16 per cent, pre-treated with human albumin. The particle size is indicated after the name of the reagent in the tests where it is used.
A white or almost white, fine, homogeneous powder.

Silica gel for chromatography, hydrophilic. 1077200.
A very finely divided silica gel whose surface has been modified to provide hydrophilic characteristics. The particle size may be stated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, nitrile. 1077300.
A very finely divided silica gel, chemically modified at the surface by the bonding of cyanopropylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.
A fine white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, nitrile R1. 1077400.
A very finely divided silica gel consisting of porous, spherical particles with chemically bonded nitrile groups. The particle size is indicated after the name of the reagent in the test where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, nitrile R2. 1119500.
Ultrapure silica gel, chemically modified at the surface by the introduction of cyanopropylsilyl groups. Less than 20 ppm of metals. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, octadecanoylaminopropylsilyl. 1115200.
A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of aminopropylsilyl groups which are acylated with octadecanoyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, octadecylsilyl. 1077500.
A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, octadecylsilyl R1. 1110100.
A very finely divided ultrapure silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups. The particle size, the pore size and the carbon loading are indicated after the name of the reagent in the tests where it is used. Less than 20 ppm of metals.

Silica gel for chromatography, octadecylsilyl R2. 1115300.
A very finely divided (15 nm pore size) ultrapure silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups (20 per cent carbon load), optimised for the analysis of polycyclic aromatic hydrocarbons. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, octadecylsilyl, base-deactivated. 1077600.
A very finely divided (3 µm-10 µm) silica gel, pretreated before the bonding of octadecylsilyl groups by careful washing and hydrolysing most of the superficial siloxane bridges to minimise the interaction with basic components. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, octadecylsilyl, end-capped. 1115400.
A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups. To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogenous powder, practically insoluble in water and in alcohol.

Silica gel for chromatography, octadecylsilyl, end-capped R1. 1115401.
A very finely divided (10 nm pore size) ultrapure silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups (19 per cent carbon load). To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used. It contains less than 20 ppm of metals.

Silica gel for chromatography, octadecylsilyl, end-capped, base-deactivated. 1108600.
A very finely divided (3 µm-10 µm) silica gel with a pore size of 10 nm and a carbon loading of 16 per cent, pre-treated before the bonding of octadecylsilyl groups by washing and hydrolysing most of the superficial siloxane bridges. To further minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the test where it is used.
4.1.1. Reagents

**Silica gel for chromatography, octadecylsilyl, end-capped, base-deactivated R1.** 1162600.
A very finely divided (3-10 µm) silica gel pre-treated before the bonding of octadecylsilox groups by washing and hydrolysing most of the superficial siloxane bridges. To further minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the test where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, octadecylsilyl, monolithic.** 1154500.
Monolithic rods of highly porous (greater than 80 per cent) metal-free silica with a bimodal pore structure, modified at the surface by the bonding of octadecylsilox groups.

**Silica gel for chromatography, octadecylsilyl, with polar incorporated groups, end-capped.** 1165100.
A very finely divided silica gel (3-10 µm). The particles are based on silica, chemically modified with a reagent providing a surface with chains having polar incorporated groups and terminating octadecyl groups. Furthermore, the packing material is end-capped. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, octylsilyl.** 1077700.
A very finely divided (3-10 µm) silica gel, chemically modified at the surface by the bonding of octylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, octylsilyl R1.** 1077701.
A very finely divided (3-10 µm) silica gel, chemically modified at the surface by the bonding of octylsilyl and methyl groups (double bonded phase). The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, octylsilyl R2.** 1077702.
Ultrapure very finely divided (10 nm pore size) silica gel, chemically modified at the surface by the bonding of octylsilyl groups (19 per cent carbon load). Less than 20 ppm of metals.

**Silica gel for chromatography, octylsilyl R3.** 1155200.
A very finely divided ultrapure silica gel, chemically modified at the surface by the bonding of octylsilyl groups and sterically protected with branched hydrocarbons at the silanes. The particle size is indicated after the name of the reagent in the tests where it is used.

**Silica gel for chromatography, octylsilyl, base-deactivated.** 1131600.
A very finely divided (3-10 µm) silica gel, pretreated before the bonding of octylsilyl groups by careful washing and hydrolysing most of the superficial siloxane bridges to minimise the interaction with basic components. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, octylsilyl, end-capped.** 1119600.
A very finely divided (3-10 µm) silica gel, chemically modified at the surface by the bonding of octylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, octylsilyl, end-capped, base-deactivated.** 1148800.
A very finely divided (3-10 µm) silica gel, pre-treated before the bonding of octylsilyl groups by washing and hydrolysing most of the superficial siloxane bridges. To further minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, octylsilyl, with polar incorporated groups, end-capped.** 1152600.
A very finely divided silica gel (3-10 µm). The particles are based on silica, chemically modified with a reagent providing a surface with chains having polar incorporated groups and terminating octyl groups. Furthermore, the packing material is end-capped. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder.

**Silica gel for chromatography, palmitamidopropylsilyl, end-capped.** 1161900.
A very finely divided silica gel (3-10 µm) silica gel, chemically modified at the surface by the bonding of palmitamidopropyl groups and end-capped with acetamidopropyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in alcohol.

**Silica gel for chromatography, phenylhexylsilyl.** 1153900.
A very finely divided silica gel, chemically modified at the surface by the bonding of phenylhexyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

**Silica gel for chromatography, phenylhexylsilyl, end-capped.** 1170600.
A very finely divided silica gel (3 µm), chemically modified at the surface by the bonding of phenylhexylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

**Silica gel for chromatography, phenylhexylsilyl, end-capped, base-deactivated.** 1110200.
A very finely divided (3-10 µm) silica gel, chemically modified at the surface by the bonding of phenyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

**Silica gel for chromatography, phenylsilyl R1.** 1075700.
A very finely divided silica gel (5 µm), chemically modified at the surface by the bonding of phenyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.
A fine, white or almost white, homogeneous powder, practically insoluble in water, in alcohol and in methylene chloride.

_Specific surface area: 8 nm._

**Carbon loading:** 5.5 per cent.

**Silica gel for chromatography, phenylsilyl, end-capped. 1154900.**

A very finely divided (5-10 µm) silica gel, chemically modified at the surface by the bonding of phenyl groups. To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

**Silica gel for chromatography, propylsilyl. 1170700.**

A very finely divided silica gel (3-10 µm), chemically modified at the surface by the bonding of propylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.

**Silica gel for chromatography, strong-anion-exchange. 1077800.**

A very finely divided silica gel (3-10 µm), chemically modified at the surface by the bonding of quaternary ammonium groups. The particle size is indicated after the name of the reagent in the tests where it is used.

**Silica gel for chromatography, trimethylsilyl. 1115500.**

A very finely divided silica gel (3-10 µm), chemically modified at the surface by the bonding of trimethylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

**Silica gel for size-exclusion chromatography. 1077900.**

A very finely divided silica gel (10 µm) with a very hydrophilic surface. The average diameter of the pores is about 30 nm. It is compatible with aqueous solutions between pH 2 and 8 and with organic solvents. It is suitable for the separation of proteins with relative molecular masses of $1 \times 10^{3}$ to $3 \times 10^{5}$.

**Silica gel G. 1076300. [112926-00-8].**

Contains about 13 per cent of calcium sulphate hemihydrate with a particle size of about 15 µm.

**Calcium sulphate content.** Place 0.25 g in a glass-stoppered flask, add 3 ml of dilute hydrochloric acid R and 100 ml of water R and shake vigorously for 30 min. Filter through a sintered-glass filter (2.1.2) and wash the residue. Carry out on the combined filtrate and washings the complexometric assay of calcium (2.2.11).

1 ml of 0.1 M sodium edetate is equivalent to 14.51 mg of CaSO$_4$,($\frac{1}{2}$)H$_2$O.

**pH (2.2.3).** Shake 1 g for 5 min with 10 ml of carbon dioxide-free water R. The pH of the suspension is about 7.

**Silica gel GF$_{254}$. 1076400. [112926-00-8].**

Contains about 13 per cent of calcium sulphate hemihydrate and about 1.5 per cent of a fluorescent indicator having an optimal intensity at 254 nm.

A fine, white or almost white, homogeneous powder with a particle size of about 15 µm.

**Calium sulphate content.** Determine by the method prescribed for silica gel G R.

**pH (2.2.3).** Complies with the test prescribed for silica gel G R.

**Fluorescence.** Examine by thin-layer chromatography (2.2.27) using silica gel GF$_{254}$ R as the coating substance. Apply separately to the plate at ten points increasing volumes from 1 µl to 10 µl of a 1 g/l solution of benzoic acid R in a mixture of 10 volumes of anhydrous formic acid R and 90 volumes of 2-propanol R. Develop over a path of 10 cm with the same mixture of solvents. After evaporating the solvents examine the chromatogram in ultraviolet light at 254 nm. The benzoic acid appears as dark spots on a fluorescent background in the upper third of the chromatogram for quantities of 2 µg and greater.

**Silica gel H. 1076500. [112926-00-8].**

A fine, white or almost white, homogeneous powder with a particle size of about 15 µm.

**pH (2.2.3).** Complies with the test prescribed for silica gel G R.

**Silica gel H, silanised. 1076600.**

_Preparation of a thin layer. See silanised silica gel HF$_{254}$ R._

A fine, white or almost white homogeneous powder which, after being shaken with water, floats on the surface because of its water-repellent properties.

**Chromatographic separation.** Complies with the test prescribed for silanised silica gel HF$_{254}$ R.

**Silica gel HF$_{254}$. 1076700.**

Contains about 1.5 per cent of a fluorescent indicator having an optimal intensity at 254 nm.

A fine, white or almost white, homogeneous powder with a particle size of about 15 µm.

**pH.** Complies with the test prescribed for silica gel G R.

**Fluorescence.** Complies with the test prescribed for silica gel GF$_{254}$ R.

**Silica gel HF$_{254}$, silanised. 1076800.**

Contains about 1.5 per cent of a fluorescent indicator having an optimal intensity at 254 nm.

A fine, white or almost white, homogeneous powder which, after shaking with water, floats on the surface because of its water-repellent properties.

_Preparation of a thin layer._ Vigorously shake 30 g for 2 min with 60 ml of a mixture of 1 volume of methanol R and 2 volumes of water R. Coat carefully cleaned plates with a layer 0.25 mm thick using a spreading device. Allow the coated plates to dry in air and then heat in an oven at 100 °C to 105 °C for 30 min.

**Chromatographic separation.** Introduce 0.1 g each of methyl laurate R, methyl myristate R, methyl palmitate R and methyl stearate R into a 250 ml conical flask. Add 40 ml of alcoholic potassium hydroxide solution R and heat under a reflux condenser on a water-bath for 1 h. Allow to cool, transfer the solution to a separating funnel by means of 100 ml of water R, acidify (pH 2 to 3) with dilute hydrochloric acid R and shake with three quantities, each of 10 ml of chloroform R. Dry the combined chloroform extracts over anhydrous sodium sulphate R, filter and evaporate.
to dryness on a water-bath. Dissolve the residue in 50 ml of chloroform R. Examine by thin-layer chromatography (2.2.27), using silanised silica gel HF254 as the coating substance. Apply to the plate at each of three separate points 10 µl of the chloroformic solution. Develop over a path of 14 cm with a mixture of 10 volumes of glacial acetic acid R, 25 volumes of water R and 65 volumes of dioxan R. Dry the plate at 120 °C for 30 min. Allow to cool, spray with a 35 g/l solution of phosphomolybdic acid R in 2-propanol R and heat at 150 °C until the spots become visible. Treat the plate with ammonia vapour until the background is white. The chromatograms show four clearly separated, well-defined spots.

Silica gel OC for chiral separations. 1146800.
A very finely divided silica gel for chromatography (5 µm) coated with the following derivative:

Silica gel OD for chiral separations. 1110300.
A very finely divided silica gel for chromatography (5 µm) coated with the following derivative:

Silicotungstic acid. H5SiW12O40,[11130-20-4].
White or yellowish-white crystals, deliquescent, very soluble in water and in alcohol. 
Storage: in an airtight container.

Silicristin. C29H52O10.(2R,3R,3aR,3bR,4S,7aR,8R)-3-hydroxy-3-hydroxymethyl-2,3-dihydro-1-benzofuran-7(6aH)-yl[chroman-4-one.
A white or almost white, crystalline powder, practically insoluble in water, soluble in acetone and in methanol.

Silidianin. C29H52O10.(3R,3aR,6R,7aR,8R,7a-Hydroxy-8-[4-hydroxy-3-methoxyphenyl]-3-hydroxymethyl-2,3-dihydro-1-benzofuran-5-yl]chroman-4-one.
White to yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

Silver diethylthiocarbamate. C29H52O10.AgNS2.(M, 256.1).
A pale-yellow or greyish-yellow powder, practically insoluble in water, soluble in pyridine.

It may be prepared as follows. Dissolve 1.7 g of silver nitrate R in 100 ml of water R. Separately dissolve 2.3 g of sodium diethylthiocarbamate R in 100 ml of water R. Cool both solutions to 10 °C, then mix and while stirring collect the yellow precipitate on a sintered-glass filter (2.1.2) and wash with 200 ml of cold water R. Dry the precipitate in vacuo for 2-3 h.

Silver diethylthiocarbamate may be used provided it has not changed in colour or developed a strong odour.

Silver manganese paper. 1078200.
Immerse strips of slow filter paper into a solution containing 8.5 g/l of manganese sulphate R and 8.5 g/l of silver nitrate R. Maintain for a few minutes and allow to dry over diphosphorus pentoxide R protected from acid and alkaline vapours.

Silver nitrate. 1078300.[7761-88-8].
See Silver nitrate (0009).

Silver nitrate reagent. 1078305.
To a mixture of 3 ml of concentrated ammonia R and 40 ml of 1 M sodium hydroxide, add 8 ml of a 200 g/l solution of silver nitrate R, dropwise, with stirring. Dilute to 200 ml with water R.

Silver nitrate solution R1. 1078301.
A 42.5 g/l solution.
Storage: protected from light.

Silver nitrate solution R2. 1078302.
An 85 g/l solution in pyridine R.
Storage: protected from light.

Silver nitrate solution, ammoniacal. 1078303.
Dissolve 2.5 g of silver nitrate R in 80 ml of water R and add dilute ammonia R1 dropwise until the precipitate has dissolved. Dilute to 100 ml with water R. Prepare immediately before use.

Silver nitrate solution in pyridine. 1078304.
An 85 g/l solution in pyridine R.
Storage: protected from light.

Silver oxide. Ag2O. (M, 231.7). 1078400.[20667-12-3].
Disilver oxide.
A brownish-black powder, practically insoluble in water and in alcohol, freely soluble in dilute nitric acid and in ammonia. 
Storage: protected from light.

Sinensetin. C20H20O7.[2306-27-6].
3′,4′,5′,6,7-Pentamethoxyflavone.
A white or almost white, crystalline powder, practically insoluble in water, soluble in alcohol.

mp: about 177 °C.
Absorbance (2.2.25). A solution in methanol R shows 3 absorption maxima, at 243 nm, 268 nm and 330 nm.
Assay. Examine by liquid chromatography (2.2.29) as prescribed in the monograph on Java tea (1229).

The content is not less than 95 per cent, calculated by the normalisation procedure.

Dihydro-β-sitosterol.
Content: minimum 95.0 per cent of C27H46O.

Stigmaster-5-en-3β-ol. 22,23-Dihydrostigmasterol.
A white or almost white powder, practically insoluble in water, sparingly soluble in tetrahydrofuran.

See the information section on general monographs (cover pages)
**Content:** minimum 75.0 per cent m/m of C₆H₅NO₃O, calculated with reference to the dried substance.

**Assay.** Gas chromatography (2.2.28), as prescribed in the monograph on Phystosterol (1911).

**Test solution.** Dissolve 0.100 g of the substance to be examined in tetrahydrofuran R and dilute to 10.0 ml with the same solvent. Introduce 100 µl of this solution into a suitable 3 ml flask and evaporate to dryness under nitrogen R. To the residue add 100 µl of a freshly prepared mixture of 50 µl of 1-methylimidazole R and 1.0 ml of heptfluoro-N-methyl-N-(trimethylsilyl)butanamide R. Close the flask tightly and heat at 100 °C for 15 min. Allow to cool. Inject 1 µl of the test solution.

**Sodium.** Na. (A, 22.99). 1078500. [7440-23-5]. A metal whose freshly cut surface is bright silver-grey. It rapidly tarnishes in contact with air and is oxidised completely to sodium hydroxide and converted to sodium carbonate. It reacts violently with water, yielding hydrogen and a solution of sodium hydroxide; soluble in anhydrous methanol, yielding hydrogen and a solution of sodium methoxide; practically insoluble in light petroleum.

**Storage:** under light petroleum or liquid paraffin.

**Sodium acetate.** 1078600. [6131-90-4]. See Sodium acetate (0411).

**Sodium acetate, anhydrous.** C₂H₃NaO₂. (M, 82.0). 1078700. [127-09-3]. Colourless crystals or granules, very soluble in water, sparingly soluble in alcohol. Loss on drying (2.2.32). Not more than 2.0 per cent, determined by drying in an oven at 105 °C.

**Sodium arsenite.** NaAsO₂. (M, 129.9). 1165900. [7784-46-5]. A white or almost white, crystalline powder or crystals, freely soluble in water, slightly soluble in alcohol.

**Sodium arsenite solution.** 1165910. Dissolve 5.0 g of sodium arsenite R in 30 ml of 1 M sodium hydroxide. Cool to 0 °C and add, while stirring, 65 ml of dilute hydrochloric acid R.

**Sodium ascorbate solution.** 1078800. [134-03-2]. Dissolve 3.5 g of sodium ascorbate R in 20 ml of 1 M sodium hydroxide. Prepare immediately before use.

**Sodium azide.** Na₃N. (M, 65.0). 1078900. [26628-22-8]. A white or almost white, crystalline powder or crystals, freely soluble in water, slightly soluble in alcohol.

**Sodium bicarbonate.** 1081300. [144-55-8]. See Sodium hydrogen carbonate R.

**Sodium bismuthate.** NaBiO₃. (M, 280.0). 1079000. [12232-99-4]. Content: minimum 85.0 per cent of NaBiO₃. A yellow or yellowish-brown powder, slowly decomposing when moist or at a high temperature, practically insoluble in cold water. Assay. Suspend 0.200 g in 1 ml of a 200 g/l solution of potassium iodide R and add 20 ml of dilute sulphuric acid R. Using 1 ml of starch solution R as indicator, titrate with 0.1 M sodium thiosulphate until an orange colour is obtained. 1 ml of 0.1 M sodium thiosulphate is equivalent to 14.00 mg of NaBiO₃.

**Sodium bromide.** 1154300. [7647-15-6]. See Sodium bromide (0190).

**Sodium butanesulphonate.** C₅H₁₀NaO₅S. (M, 160.2). 1115600. [2386-54-1]. A white or almost white, crystalline powder, soluble in water. mp: greater than 300 °C.

**Sodium carbonate.** 1079200. [6132-02-1]. See Sodium carbonate decahydrate (0191).

**Sodium carbonate, anhydrous.** Na₂CO₃. (M, 106.0). 1079300. [497-19-8]. Disodium carbonate. A white or almost white powder, hygroscopic, freely soluble in water. When heated to about 300 °C it loses not more than 1 per cent of its mass.

**Storage:** in an airtight container.

**Sodium carbonate solution.** 1079301. A 106 g/l solution of anhydrous sodium carbonate R.

**Sodium carbonate solution R1.** 1079302. A 20 g/l solution of anhydrous sodium carbonate R in 0.1 M sodium hydroxide.

**Sodium carbonate solution R2.** 1079303. A 40 g/l solution of anhydrous sodium carbonate R in 0.2 M sodium hydroxide.

**Sodium carbonate monohydrate.** Na₂CO₃·H₂O. 1131700. [5968-11-6]. See Sodium carbonate monohydrate (0192).

**Sodium cetostearyl sulphate.** 1079400. See Sodium cetostearyl sulphate (0847).

**Sodium chloride.** 1079500. [7647-14-5]. See Sodium chloride (0193).

**Sodium chloride solution.** 1079502. A 20 per cent m/m solution.

**Sodium chloride solution, saturated.** 1079503. Mix 1 part of sodium chloride R with 2 parts of water R, shake from time to time and allow to stand. Before use, decant the solution from any undissolved substance and filter, if necessary.

**Sodium citrate.** 1079600. [6132-04-3]. See Sodium citrate (0412).

**Sodium cobaltinitrite.** Na₃[Co(NO₂)₆]. (M, 403.9). 1079700. [13600-98-1]. Trisodium hexanitrocobaltate(III). Orange-yellow powder, freely soluble in water, slightly soluble in alcohol.

**Sodium cobaltinitrite solution.** 1079701. A 100 g/l solution. Prepare immediately before use.

**Sodium decanesulphonate.** C₁₀H₂₁NaO₅S. (M, 244.3). 1079800. [13419-61-9]. Crystalline powder or flakes, white or almost white, freely soluble in water, soluble in methanol.

**Sodium decyl sulphate.** C₁₅H₃₁NaO₄S. (M, 260.3). 1138600. [142-87-0]. Content: minimum 95.0 per cent of C₁₅H₃₁NaO₄S. White or almost white powder, freely soluble in water.

**Sodium deoxycholate.** C₂₄H₃₉NaO₄. (M, 414.6). 1138000. [302-95-4]. Sodium 3α,12α-dihydroxy-5β-cholan-24-oate.
Sodium deoxyribonucleate. (About 85 per cent has a relative molecular mass of 2 x 10^7 or greater). 1079900. [73049-39-5].

A white or almost white, fibrous preparation obtained from calf thymus.

Test for suitability. Dissolve 10 mg in imidazole buffer solution pH 6.5 R and dilute to 10.0 ml with the same buffer solution (solution a). Dilute 2.0 ml of solution (a) to 50.0 ml with imidazole buffer solution pH 6.5 R. The absorbance (2.2.25) of the solution, measured at 260 nm, is 0.4 to 0.8. To 0.5 ml of solution (a) add 0.5 ml of imidazole buffer solution pH 6.5 R and 3 ml of perchloric acid (25 g/l HClO4). A precipitate is formed. Centrifuge and collect the supernatant liquid, measured at 260 nm using a mixture of 1 ml of imidazole buffer solution pH 6.5 R and 3 ml of perchloric acid (25 g/l HClO4) as compensation liquid, is not greater than 0.3.

In each of two tubes, place 0.5 ml of solution (a) and 0.5 ml of a solution of streptodornase containing 10 IU/ml in imidazole buffer solution pH 6.5 R. To one tube add immediately 3 ml of perchloric acid (25 g/l HClO4). A precipitate is formed. Centrifuge and collect the supernatant liquid (a). Heat the other tube at 37 °C for 15 min and add 3 ml of perchloric acid (25 g/l HClO4). Centrifuge and collect the supernatant liquid (b). The absorbance of supernatant liquid (b), measured at 260 nm with reference to supernatant liquid (a) is not less than 0.15.

Sodium dihydrogen phosphate. \( \text{Na}_2\text{HPO}_4\cdot\text{H}_2\text{O} \). (M, 225.3). 1080000. [20624-25-3].

A white or almost white, waxy solid.

Sodium dihydrogen phosphate, anhydrous. \( \text{Na}_2\text{HPO}_4 \). (M, 120.0). 1080200. [7558-80-7].

White or almost white powder, hygroscopic.

Storage: in an airtight container.

Sodium dihydrogen phosphate monohydrate. \( \text{Na}_2\text{HPO}_4\cdot\text{H}_2\text{O} \). (M, 138.0). 1080300. [10049-21-5].

A white or almost white, slightly deliquescent crystals or granules, freely soluble in water, practically insoluble in alcohol.

Storage: in an airtight container.

Sodium diocetyl sulfosuccinate. \( \text{C}_{18}\text{H}_{35}\text{NaO}_3\text{S},\text{H}_2\text{O} \). (M, 444.6). 1170800. [5777-11-7].

Sodium 1,4-bis(2-ethylhexyloxy)-1,4-dioxobutane-2-sulfonate. A white or almost white, waxy solid.

Sodium dithionate. \( \text{Na}_2\text{S}_2\text{O}_4 \). (M, 174.1). 1080400. [7775-14-6].

White or greyish-white, crystalline powder, oxidises in air, very soluble in water, slightly soluble in alcohol.

Storage: in an airtight container.

Sodium dodecyl sulphate. 1080500. [151-21-3].

See Sodium laurylsulphate (0098) except for the content which should be not less than 99.0 per cent.

Sodium edetate. 1080600. [6381-92-6].

See Disodium edetate (0232).
A white or almost white, crystalline powder or colourless crystals, hygroscopic, freely soluble in water, soluble in alcohol.
Storage: in airtight container.

Sodium iodide. 1081800. 7681-82-5. See Sodium iodide (0196).

Sodium laurilsulfate. 1081900. 151-21-3. See Sodium laurilsulfate (0098).

White or almost white powder or crystals, freely soluble in water.
Absorbance A₁% in (2.2:25), determined in water R:
about 0.05 at 210 nm,
about 0.03 at 220 nm,
about 0.02 at 230 nm,
about 0.02 at 500 nm.

Sodium metabisulphite. 1082000. 7681-57-4. See Sodium metabisulphite (0849).

Sodium methanesulphonate. CH₃SO₃Na. (M₀ 118.1). 1082100. 2386-57-4.
A white or almost white, crystalline powder, hygroscopic.
Storage: in an airtight container.

A white or almost white, crystalline powder or colourless crystals, freely soluble in water.

Sodium naphthoquinonesulphonate. C₁₄H₈NaO₃S. (M₀ 260.2). 1082300. 521-24-4. Sodium 1,2-naphthoquinone-4-sulphonate.
A yellow to orange-yellow, crystalline powder, freely soluble in water, practically insoluble in alcohol.

White or almost white powder or granules or colourless, transparent crystals, deliquescent in moist air, freely soluble in water, slightly soluble in alcohol.
Storage: in an airtight container.

Sodium nitrite. NaNO₂. (M₀ 69.0). 1082500. 7632-00-0.
Content: minimum 97.0 per cent of NaNO₂.
A white or almost white, granular powder or a slightly yellow, crystalline powder, freely soluble in water.
Assay. Dissolve 0.100 g in 50 ml of water R. Add 50.0 ml of 0.02 M potassium permanganate and 15 ml of dilute sulphuric acid R. Add 3 g of potassium iodide R. Titrate with 0.1 M sodium thiosulphate, using 1.0 ml of starch solution R added towards the end of the titration as indicator.
1 ml of 0.02 M potassium permanganate is equivalent to 3.450 mg of NaNO₂.

Sodium nitrite solution. 1082501.
A 100 g/l solution. Prepare immediately before use.
4.1.1. Reagents

Sodium nitroprusside. \( \text{Na}_2[\text{Fe(CN)}_5(\text{NO})]_2\text{H}_2\text{O.} \) 1082600. [13755-38-9]. Sodium pentacyano-nitrosylferrate(III) dihydrate.
Reddish-brown powder or crystals, freely soluble in water, slightly soluble in alcohol.

**Sodium octanesulphonate.** \( \text{C}_8\text{H}_{17}\text{NaO}_3\text{S.} \) 1082700. [5324-84-5].

**Content:** minimum 98.0 per cent of \( \text{C}_8\text{H}_{17}\text{NaO}_3\text{S.} \)

White or almost white, crystalline powder or flakes, freely soluble in water, soluble in methanol.

**Absorbance.** The absorbance (2.2.25) of a 54 g/1 solution measured at 200 nm is not greater than 0.10 and that measured at 250 nm is not greater than 0.01.

**Sodium octyl sulphate.** \( \text{C}_8\text{H}_{17}\text{NaO}_4\text{S.} \) [174.2].

White or almost white, crystalline solid, soluble in water.

**Sodium periodate solution.** 1083900. [10102-15-5].

Dissolve 12 g of sodium periodate \( \text{R} \) with heating in 45 ml of a mixture of 10 volumes of \( \text{water} \) \( \text{R} \) and 29 volumes of glycerol (85 per cent) \( \text{R} \), allow to cool and dilute to 100 ml with the same mixture of solvents.

The solution should be colourless.

**Sodium sulphate decahydrate.** \( \text{Na}_2\text{SO}_4\cdot10\text{H}_2\text{O.} \) 1083900. [7775-83-7].

See Sodium sulphite (0413).

**Sodium sulphate, anhydrous.** 1083800. [7775-82-6].

Ignite at 600 °C to 700 °C anhydrous sodium sulphate complying with the requirements prescribed in the monograph on Anhydrous sodium sulphate (0099).

**Loss on drying (2.2.32):** maximum 0.5 per cent, determined by drying in an oven at 130 °C.

**Sodium sulphide.** \( \text{Na}_2\text{S}_3\cdot9\text{H}_2\text{O.} \) 1083900. [1313-84-4]. Disodium sulphide nonahydrate.

Colourless, rapidly yellowing crystals, deliquescent, very soluble in water.

**Storage:** in an airtight container.

**Sodium sulphide solution.** 1083901.

Dissolve 12 g of sodium sulphide \( \text{R} \) with heating in 45 ml of a mixture of 10 volumes of \( \text{water} \) \( \text{R} \) and 29 volumes of glycerol (85 per cent) \( \text{R} \), allow to cool and dilute to 100 ml with the same mixture of solvents.

The solution should be colourless.

**Sodium sulphide solution R1.** 1083902.

Prepare by one of the following methods.

- Dissolve 5 g of sodium sulphide \( \text{R} \) in a mixture of 10 ml of \( \text{water} \) \( \text{R} \) and 30 ml of glycerol.

- Dissolve 5 g of sodium hydroxide \( \text{R} \) in a mixture of 30 ml of \( \text{water} \) \( \text{R} \) and 90 ml of glycerol. Divide the solution into 2 equal portions. Saturate 1 portion with hydrogen sulphide \( \text{R} \), with cooling. Mix the 2 portions.

**Storage:** in a well-filled container, protected from light; use within 3 months.

**Sodium sulphite.** 1084000. [10102-15-5].

See Sodium sulphite heptahydrate (0776).

**Sodium sulphite, anhydrous.** 1084100. [7775-83-7].

See Anhydrous sodium sulphite (0775).

**Sodium tartrate.** \( \text{C}_6\text{H}_8\text{Na}_2\text{O}_7\cdot2\text{H}_2\text{O.} \) 1084200. [6106-24-7].

Disodium (2R,3R)-2,3-dihydroxybutanedioate dihydrate.

White or almost white crystals or granules, very soluble in water, practically insoluble in alcohol.

**Sodium taurodeoxycholate.** \( \text{C}_2\text{H}_{32}\text{NaO}_6\text{S}_3\text{H}_2\text{O.} \) 1155600. [110026-03-4]. Sodium 2-(3,12-dihydroxy-5-cholan-24-oyl)amino[ethanesulphonate.
Sodium tetraphenylborate. \( \text{NaB(C}_6\text{H}_5\text{)}_4 \). (\( \text{NaBH}_4 \)).

Sodium tetrahydroborate. Water and deuterium oxide mp: about 300 °C.

A white or almost white, crystalline powder, freely soluble in water, in ethanol and in methanol. The degree of deuteration is not less than 99 per cent.

Sodium tetrahydroborate reducing solution. 1146901. Introduce about 100 ml of water into a 500 ml volumetric flask containing a stirring bar. Add 5.0 g of sodium hydroxide in pellets and 2.5 g of sodium tetrahydroborate. Stir until complete dissolution, dilute to 500.0 ml with water and mix. Prepare immediately before use.

Sodium tetr phenyl borate solution. A1 0g / l solution. Immediately before use.

Sodium tetr phenyl borate reducing solution. 1146901. Introduce about 100 ml of water into a 500 ml volumetric flask containing a stirring bar. Add 5.0 g of sodium hydroxide in pellets and 2.5 g of sodium tetrahydroborate. Stir until complete dissolution, dilute to 500.0 ml with water and mix. Prepare immediately before use.

Sodium tetrah ydroborate. \( \text{NaBH}_4 \). (M, 37.8). 1146900. [16940-66-2]. Sodium borohydride.

Water and deuterium oxide maximum 0.5 per cent.

A white or slightly yellowish, bulky powder, freely soluble in water and in acetone.

Sodium tetraphenyl borate reducing solution. 11084401. Filter before use if necessary. A 10 g/1 solution.

Storage: use within 1 week.

Sodium thioglycollate. \( \text{C}_2\text{H}_3\text{NaO}_2\text{S} \). (M, 114.1). 1084500. [367-51-1]. Sodium mercaptoacetate.

White or almost white, granular powder or crystals, hygroscopic, freely soluble in water and in methanol, slightly soluble in alcohol. 

Storage: in an airtight container.

Sodium thiosulphate. 1084600. [10102-17-7]. See Sodium thiosulphate (0414).

Sodium tungstate. \( \text{Na}_2\text{WO}_4\text{.2H}_2\text{O} \). (M, 329.9). 1084700. [10213-10-2]. Disodium tungstate dihydrate.

A white or almost white, crystalline powder or colourless crystals, freely soluble in water forming a clear solution, practically insoluble in alcohol.

Sorbitol. 1084800. [50-70-4]. See Sorbitol (0435).

Squalane. \( \text{C}_\text{26}\text{H}_4\text{O}_2\text{.2H}_2\text{O} \). 1084900. [111-01-3]. 2,6,10,15,19,23-Hexamethyltetraicosane.

A colourless, oily liquid, freely soluble in fatty oils, slightly soluble in acetone, in alcohol, in glacial acetic acid and in methanol.

\( \text{d}_20^0 = 0.811 \) to 0.813.

\( \text{n}_{D}^0 = 1.451 \) to 1.453.

**Stannous chloride.** \( \text{SnCl}_2\text{.2H}_2\text{O} \). (M, 225.6). 1085000. [10025-69-1]. Tin dichloride dihydrate.

Content: minimum 97.0 per cent of \( \text{SnCl}_2\text{.2H}_2\text{O} \).

Colourless crystals, very soluble in water, freely soluble in alcohol, in glacial acetic acid and in dilute and concentrated hydrochloric acid.

Assay. Dissolve 0.500 g in 15 ml of hydrochloric acid in a ground-glass-stoppered flask. Add 10 ml of water and 5 ml of chloroform. Titrate rapidly with 0.05 M potassium iodate until the chloroform layer is colourless.

1 ml of 0.05 M potassium iodate is equivalent to 22.56 mg of \( \text{SnCl}_2\text{.2H}_2\text{O} \).

Stannous chloride solution. 1085001. Heat 20 g of \( \text{SnCl}_2\text{.2H}_2\text{O} \) with 85 ml of hydrochloric acid until no more hydrogen is released. Allow to cool.

Storage: over an excess of \( \text{SnCl}_2\text{.2H}_2\text{O} \), protected from air.

Stannous chloride solution R1. 1085002. Immediately before use, dilute 1 volume of stannous chloride solution R with 10 volumes of dilute hydrochloric acid R.

Stannous chloride solution R2. 1085003. To 8 g of stannous chloride R add 100 ml of a 20 per cent \( V/V \) solution of hydrochloric acid R. Shake until dissolved, heating, if necessary, on a water-bath at 50 °C. Pass a current of nitrogen R for 15 min. Prepare immediately before use.

Stanolone. \( \text{C}_{19}\text{H}_{30}\text{O}_2 \). (M, 290.4). 1154400. [521-186]. 17β-Hydroxy-5α-androstan-3-one.

White or almost white powder.

mp: about 180 °C.

Standard solution for the micro determination of water. 1147300.

Commercially available standard solution for the coulometric titration of water, containing a certified content of water in a suitable solvent.

**Staphylococcus aureus strain V8 protease.** Type XVII-B. 1115800. [66676-43-5]. Microbial extracellular proteolytic enzyme. A lyophilised powder containing 500 units to 1000 units per milligram of solid.

**Starch, soluble.** 1085100. [9005-84-9].

A white or almost white powder.

Prepare a 20 g/1 solution in hot water R. The solution is at most slightly opalescent and remains fluid on cooling.

**Starch iodate paper.** 1085101. Immerse strips of filter paper in 100 ml of iodide-free starch solution R containing 0.1 g of potassium iodate R. Drain and allow to dry protected from light.

**Starch iodide paper.** 1085106. Immerse strips of filter paper in 100 ml of starch solution R containing 0.5 g of potassium iodide R. Drain and allow to dry protected from light.

**Test for sensitivity.** Mix 0.05 ml of 0.1 M sodium nitrite with 4 ml of hydrochloric acid R and dilute to 100 ml with water R. Apply one drop of the solution to starch iodide paper; a blue spot appears.
Starch solution. 1085103.
Triturate 1.0 g of soluble starch with 5 ml of water and whilst stirring pour the mixture into 100 ml of boiling water containing 10 mg of mercuric iodide R. Carry out the test for sensitivity each time the reagent is used.

Test for sensitivity. To a mixture of 1 ml of the starch solution and 20 ml of water, add about 50 mg of potassium iodide R and 0.05 ml of iodine solution R1. The solution is blue.

Starch solution, iodide-free. 1085104.
Prepare the solution as prescribed for starch solution R, omitting the mercuric iodide. Prepare immediately before use.

Starch solution R1. 1085105.
Mix 1 g of soluble starch with 5 ml of water and whilst stirring pour the mixture into 100 ml of boiling water. Use a freshly prepared solution.

Test for sensitivity. To a mixture of 1 ml of the starch solution and 20 ml of water, add about 50 mg of potassium iodide R and 0.05 ml of iodine solution R1. The solution is blue.

Stearic acid. C18H36O2. (M 284.5). 1085200. [57-11-4]. Octadecanoic acid.
White or almost white powder or flakes, greasy to the touch, practically insoluble in water, soluble in hot alcohol.
mp: about 70 °C.
Stearic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional requirement.

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Saw palmetto fruit (1848). The content of stearic acid is not less than 98 per cent, calculated by the normalisation procedure.

mp: about 60 °C.
Content: minimum 95 per cent of C18H38O.

White or almost white powder, insoluble in water.
mp: about 170 °C. \[\alpha_d^{24}\] : about −51 (c 2 in chloroform).

Streptomycin sulphate. 1085300. [3810-74-0].
See Streptomycin sulphate (0053).

Strongly acidic ion-exchange resin. 1085400.
See ion-exchange resin, strongly acidic R.

Strontium carbonate. SrCO3. (M 147.6). 1122700. [1639-05-2].
A white or almost white, crystalline powder.
Content: minimum 99.5 per cent of SrCO3.

Strontium chloride hexahydrate. SrCl2, 6H2O. (M 266.6). 1167000. [10025-70-4].
White or almost white crystals, very soluble in water.
mp: about 115 °C (loss of water) and 872 °C.

Strontium selective extraction resin. 1167100.
Commercially available resin prepared by loading a suspension of 4,4’-(5’)-di-tert-butylcyclohexano-18-crown-6 (crown ether) in octanol onto an inert chromatographic support. The bed density of this resin is approximately 0.35 g/ml.

Strontium-85 spiking solution. 1166800.
Dilute strontium-85 standard solution R to a radioactivity concentration of approximately 10 kBq/ml with a 0.27 g/l solution of strontium chloride hexahydrate R in a 1.03 g/l solution of hydrochloric acid R.

Strontium-85 standard solution. 1166900.
A solution of strontium-85 in the form of Sr2+ ions in a 51.5 g/l solution of hydrochloric acid R.

bp: about 145 °C.
Colourless, oily liquid, very slightly soluble in water.

Styrene-divinylbenzene copolymer. 1085500.
Porous, rigid, cross-linked polymer beads. Several grades are available with different sizes of beads. The size range of the beads is specified after the name of the reagent in the tests where it is used.

A white or almost white, crystalline powder or colourless crystals, soluble in water and in alcohol.
mp: 184 °C to 187 °C.

Sucrose. 1085700. [57-50-1].
See Sucrose (0204).

Sudan orange. C16H12N2O. (M 248.3). 1110700. [842-07-9].
Colour Index No. 12150. Schultz No. 1141700. 1-(Phenylazo)naphthalen-2-ol. Sudan I.
An orange-red powder, practically insoluble in water, soluble in methylene chloride.
mp: about 131 °C.

Sudan red G. C17H14N2O2. (M 278.3). 1085800. Schulz No. 149.
Colour Index No. 12150. 1-(2-Methoxyphenyl)azo)naphthalen-2-ol. Sudan II.
A reddish-brown powder, practically insoluble in water.
Chromatography. Examine by thin-layer chromatography (2.2.27) using silica gel G R as the coating substance. Apply 10 µl of a 0.1 g/l solution in methylene chloride R and develop over a path of 10 cm with the same solvent. The chromatogram shows only one principal spot.
4-Aminobenzensulphonamide.
A white or almost white powder, slightly soluble in water, freely soluble in boiling water, in acetone, in dilute acids and in solutions of the alkali hydroxides, sparingly soluble in alcohol and in light petroleum.
mp: about 165 °C.

Sulphamic acid. H₂N₂O₃S. (M, 97.1). 1085900. [5329-14-6].
White or almost white crystalline powder or crystals, freely soluble in water, sparingly soluble in acetone, in alcohol and in methanol.
mp: about 205 °C, with decomposition.

Sulphan blue. C₆H₇NO₃S. (Sulphanilic acid. M, 190.1). 1086200. [129-17-9].
Schultz No. 769.
Colour Index No. 42045.
Acid Blue 1. Patent Blue VF. Disulphine blue. Blue VS. Sodium [[[(4-diethylamino)phenyl](2,4-dihydroxyphenyl)methylene]cyclohexa-2,5-dien-1-ylidene]diethylammonium.
A violet powder, soluble in water. Dilute solutions are blue and turn yellow on the addition of concentrated hydrochloric acid.

Colourless crystals, sparingly soluble in water, practically insoluble in alcohol.

Sulphanilic acid solution. 1086203.
Dissolve 0.33 g of sulphanilic acid R in 75 ml of water R heating gently if necessary and dilute to 100 ml with glacial acetic acid R.

Sulphanilic acid solution R1. 1086201.
Dissolve 0.5 g of sulphanilic acid R in a mixture of 75 ml of dilute acetic acid R and 75 ml of water R.

Sulphanilic acid solution, diazotised. 1086202.
Dissolve, with warming, 0.9 g of sulphanilic acid R in 9 ml of hydrochloric acid R, and dilute to 100 ml with water R. Cool 10 ml of this solution in iced water and add 10 ml of an ice-cold 45 g/l solution of sodium nitrite R. Allow to stand at 0 °C for 15 min (if stored at this temperature, the solution is stable for 3 days) and immediately before use add 20 ml of a 100 g/l solution of sodium carbonate R.

White or yellowish-white powder or crystals, very slightly soluble in water, soluble in acetone, slightly soluble in alcohol. It dissolves in dilute mineral acids and in solutions of alkali hydroxides and carbonates.
mp: about 200 °C.

Sulphomolybdic reagent R2. 1086400.
Dissolve about 50 mg of ammonium molybdate R in 10 ml of sulphuric acid R.

Sulphomolybdic reagent R3. 1086500.
Dissolve with heating 2.5 g of ammonium molybdate R in 20 ml of water R. Dilute 28 ml of sulphuric acid R in 50 ml of water R, then cool. Mix the two solutions and dilute to 100 ml with water R.
Storage: in a polyethylene container.

A white or almost white, crystalline powder or crystals, very soluble in water and in alcohol.
mp: about 109 °C.

Sulphur. 1110800. [7704-34-9].
See Sulphur for external use (0953).

Sulphur dioxide. SO₂. (M, 64.1). 1086700. [7446-09-5].
Sulphurous anhydride.
A colourless gas. When compressed it is a colourless liquid.

Sulphur dioxide R1. SO₂. (M, 64.1). 1110900.
Content: minimum 99.9 per cent V/V of SO₂.

Sulphuric acid. H₂SO₄. (M, 98.1). 1086800. [7664-93-9].
Content: 95.0 per cent m/m to 97.0 per cent m/m of H₂SO₄.
A colourless, caustic liquid with an oily consistency, highly hygroscopic, miscible with water and with alcohol producing intense heat.
δ₀.⁰₁ \text{SO}_₂ = 1.834 to 1.837.
A 10 g/l solution is strongly acid and gives the reactions of sulphates (2.3.1).

Appearance. It is clear (2.2.1) and colourless (2.2.2, Method II).

Oxidisal substances. Pour 20 g cautiously, with cooling, into 40 ml of water R. Add 0.5 ml of 0.002 M potassium permanganate. The violet colour persists for at least 5 min.

Chlorides. Pour 10 g, carefully and while cooling, into 10 ml of water R and after cooling dilute to 20 ml with the same solvent. Add 0.5 ml of silver nitrate solution R2. Allow to stand for 2 min protected from bright light. The solution is not more opalescent than a standard prepared at the same time using a mixture of 1 ml of chloride standard solution (5 ppm Cl) R, 19 ml of water R and 0.5 ml of silver nitrate solution R2 (0.5 ppm).

Nitrates. Pour 50 g or 27.2 ml, carefully and while cooling, into 15 ml of water R. Add 0.2 ml of a freshly prepared 50 g/l solution of brucine R in glacial acetic acid R. After 5 min any colour is less intense than that of a reference mixture prepared in the same manner and containing 12.5 ml of water R, 50 g of nitrogen-free sulphuric acid R, 2.5 ml of nitrate standard solution (10 ppm NO₃) R and 0.2 ml of a 50 g/l solution of brucine R in glacial acetic acid R (0.5 ppm).

Ammonium. Pour 2.5 g, carefully and while cooling, into water R and dilute to 20 ml with the same solvent. Cool, and add dropwise 10 ml of a 200 g/l solution of sodium hydroxide R, followed by 1 ml of alkaline potassium tetraiodomercurate solution R. The colour of the solution is less intense than that of a mixture of 5 ml of ammonium standard solution (1 ppm NH₄) R, 15 ml of water R, 10 ml of a 200 g/l solution of sodium hydroxide R and 1 ml of alkaline potassium tetraiodomercurate solution R (2 ppm).

Arsenic (2.4.2). To 50 g add 3 ml of nitric acid R and evaporate carefully until the volume is reduced to about 10 ml. Cool, add to the residue 20 ml of water R and concentrate to 5 ml. The solution complies with limit test A for arsenic (0.02 ppm). Prepare the standard using 1.0 ml of arsenic standard solution (1 ppm As) R.

Heavy metals (2.4.8). Dilute 10 ml of the solution obtained in the test for iron to 20 ml with water R. 12 ml of the solution complies with limit test A for heavy metals (2 ppm). Prepare the standard using lead standard solution (2 ppm Pb) R.
Iron (2.4.9). Dissolve the residue on ignition with slight heating in 1 ml of dilute hydrochloric acid R and dilute to 50.0 ml with water R. 5 ml of the solution diluted to 10 ml with water R complies with the limit test for iron (1 ppm).

Residue on ignition: maximum 0.001 per cent, determined on 100 g by evaporating cautiously in a small crucible over a naked flame and igniting the residue to redness.

Assay. Weigh accurately a ground-glass-stoppered flask containing 30 ml of water R, introduce 0.8 ml of the sulphuric acid, cool and weigh again. Titrate with 1 M sodium hydroxide, using 0.1 ml of methyl red solution R as indicator.

1 ml of 1 M sodium hydroxide is equivalent to 49.04 mg of H₂SO₄.

Storage: in a ground-glass-stoppered container made of glass or other inert material.

**Sulphuric acid, alcoholic, 2.5 M. 1086801.**

Carefully and with constant cooling, stir 14 ml of sulphuric acid R into 60 ml of ethanol R. Allow to cool and dilute to 100 ml with ethanol R. Prepare immediately before use.

**Sulphuric acid, alcoholic, 0.25 M. 1086802.**

Dilute 10 ml of 2.5 M alcoholic sulphuric acid R to 100 ml with ethanol R. Prepare immediately before use.

**Sulphuric acid, alcoholic solution. 1086803.**

Carefully and with constant cooling, stir 20 ml of sulphuric acid R into 60 ml of alcohol R. Allow to cool and dilute to 100 ml with alcohol R. Prepare immediately before use.

**Sulphuric acid, dilute. 1086804.**

Contains 98 g/l of H₂SO₄.

Add 5.5 ml of sulphuric acid R to 60 ml of water R, allow to cool and dilute to 100 ml with the same solvent.

Assay. Into a ground-glass-stoppered flask containing 30 ml of water R, introduce 10.0 ml of the dilute sulphuric acid. Titrate with 1 M sodium hydroxide, using 0.1 ml of methyl red solution R as indicator.

1 ml of 1 M sodium hydroxide is equivalent to 49.04 mg of H₂SO₄.

**Sulphuric acid-formaldehyde reagent. 1086805.**

Mix 2 ml of formaldehyde solution R with 100 ml of sulphuric acid R.

**Sulphuric acid, heavy metal-free. 1086807.**

Complies with the requirements prescribed for sulphuric acid R and with the following maximum contents of heavy metals:

As: 0.005 ppm;
Cd: 0.002 ppm;
Cu: 0.001 ppm;
Fe: 0.05 ppm;
Hg: 0.005 ppm;
Ni: 0.002 ppm;
Ph: 0.001 ppm;
Zn: 0.005 ppm.

**Sulphuric acid, nitrogen-free. 1086806.**

Complies with the requirements prescribed for sulphuric acid R and with the following additional test.

Nitrates. To 5 ml of water R add carefully 45 ml of the sulphuric acid, allow to cool to 40 °C and add 8 mg of diphenylbenzidine R. The solution is faint pink or very pale blue.

**Sulphuric acid, nitrogen-free R1. 1086808.**

Nitrogen-free sulphuric acid R containing 95.0 per cent m/m to 95.5 per cent m/m of H₂SO₄.

**Sunflower oil. 1086900.**

See Sunflower oil, refined (1371).

**Swertiamarin. C₆H₁₂O₄. (M, 154.3). 1163600.**


**Tagatose. C₆H₁₂O₆. (M, 180.16). 1111000.**

87-81-0. D-Glyo-Hexulose.

White or almost white powder.

([α]D): +2.3 (21.9 g/l solution in water R).

mp: 134 °C to 135 °C.

**Talc. 1087000.**

14807-96-6. See Talc (0438).

**Tannic acid. 1087100.**

1401-55-4. Yellowish to light-brown, glistening scales or amorphous powder, very soluble in water, freely soluble in alcohol, soluble in acetone.

**Tartaric acid. 1087200.**

87-69-4. See Tartaric acid (0460).

**Taxifolin. C₁₆H₂₂O₁₀. (M, 310.34). 1151800.**

[80-18-2]. (2R,3R)-2,3-Dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydro-4H-1-benzopyran-4-one.

White or almost white powder, slightly soluble in ethanol.

A solution in ethanol R shows an absorption maximum (2.2.25) at 290 nm.

**Tecnazene. C₆HCl₄NO₂. (M, 260.9). 1132400.**

117-18-0. bp: about 304 °C.

mp: 99 °C to 100 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

**α-Terpinene. C₁₀H₁₆. (M, 136.2). 1163600.**

[99-85-4]. 1-Isopropyl-4-methylcyclohexa-1,3-diene.

Clear, almost colourless liquid.

[α]D: +0.73.

nD: 1.478.

bp: about 174 °C.

**α-Terpinene used in gas chromatography complies with the following additional test.**

Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph on Tea tree oil (1837).

**γ-Terpinene. C₁₀H₁₆. (M, 136.2). 1115900.**

99-85-4. 1-Isopropyl-4-methylcyclohexa-1,4-diene.

An oily liquid.

**γ-Terpinene used in gas chromatography complies with the following additional test.**

See the information section on general monographs (cover pages)
Assay. Examine by gas chromatography (2.2.28) as prescribed in the monograph Peppermint oil (0405).

**Test solution.** The substance to be examined.

The area of the principal peak is not less than 97.0 per cent of the area of all the peaks in the chromatogram obtained.

**Terpinol-4-ol.** C_{10}H_{16}. (M, 154.2). 1116000. [562-74-3]. 4-Methyl-1-(1-methylethyl)cyclohex-3-en-1-ol.

p-Menth-1-en-4-ol.

An oily, colourless liquid. Terpinol-4-ol used in gas chromatography complies with the following additional test.

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Lavender oil (1338).

**Test solution.** The substance to be examined.

The area of the principal peak is not less than 90.0 per cent of the area of all the peaks in the chromatogram obtained.

**α-Terpineol.** C_{16}H_{36}O. (M, 154.2). 1087200. [98-55-5]. (RS)-2-(4-Methylcyclohex-3-enyl)-2-propanol.

Colourless crystals, practically insoluble in water, soluble in alcohol. $d_20^0$: about 0.935. $n_20^0$: about 1.483. $[a]_p^20$: about 92.5. mp: about 35 °C.

It may contain 1 to 3 per cent of β-terpineol.

α-Terpineol used in gas chromatography complies with the following test.

**Assay.** Examine by gas chromatography (2.2.28) under the conditions described in the monograph on Anise oil (0804).

**Test solution.** A 100 g/l solution in hexane R.

The area of the principal peak is not less than 97.0 per cent of the total area of the peaks. Disregard the peak due to hexane.

**Terpinolene.** C_{10}H_{18}O. (M, 136.2). 1140400. [586-62-9]. p-Mentha-1,4(8)-diene. 4-Isopropylidene-1-methylcyclohexene.

Clear, almost colourless liquid. $d_20^0$: about 0.863. $n_20^0$: about 1.488. bp: about 184 °C.

**Terpinolene used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Tea tree oil (1837).

The content is not less than 90 per cent, calculated by the normalisation procedure.

**Testosterone.** 1116100. [58-22-0]. See Testosterone (1373).

**Testosterone propionate.** 1087400. [57-85-2]. See Testosterone propionate (0297).

**Tetrahydroammonium bromide.** C_{16}H_{16}BrN. (M, 322.4). 1087500. [1643-19-2].

White or almost white crystals. mp: 102 °C to 104 °C.

**Tetrahydroammonium dihydrogen phosphate.** C_{16}H_{36}NO_4P. (M, 339.5). 1087600. [5574-97-0].

White or almost white powder, hygroscopic. pH (2.2.3): about 7.5 for a 170 g/l solution. Absorbance (2.2.25): about 0.10 determined at 210 nm using a 170 g/l solution.

**Storage:** in an airtight container.

**Tetrahydroammonium hydrogen sulphate.** C_{16}H_{36}NO_4S. (M, 339.5). 1087700. [32503-27-8].

A crystalline powder or colourless crystals, freely soluble in water and in methanol.

mp: 169 °C to 173 °C.

Absorbance (2.2.25). The absorbance of a 50 g/l solution, at wavelengths from 240 nm to 300 nm, is not greater than 0.05.

**Tetrahydroammonium hydrogen sulphate R1.** 1087701.

Complies with the requirements prescribed for tetrahydroammonium hydrogen sulphate R and with the following additional requirement:

Absorbance (2.2.25). The absorbance of a 50 g/l solution, at wavelengths from 215 nm to 300 nm, is not greater than 0.02.

**Tetrahydroammonium hydroxide.** C_{16}H_{36}NO_30H_2O. (M, 800). 1087800. [2052-49-5].

**Content:** minimum 98.0 per cent of C_{16}H_{36}NO_30H_2O.

White or almost white crystals, soluble in water.

**Assay.** Dissolve 1.000 g in 100 ml of water R. Titrate immediately with 0.1 M hydrochloric acid determining the end-point potentiometrically (2.2.20). Carry out a blank titration.

1 ml of 0.1 M hydrochloric acid is equivalent to 80.0 mg C_{16}H_{36}NO_30H_2O.

**Tetrahydroammonium hydroxide solution (104 g/l).** 1087801. [2052-49-5].

A solution containing 104 g/l of C_{16}H_{36}NO (M, 259.5), prepared by dilution of a suitable reagent grade.

**Tetrahydroammonium hydroxide solution (400 g/l).** 1087802. [2052-49-5].

A solution containing 400 g/l of C_{16}H_{36}NO (M, 259.5) of a suitable grade.

**Tetrahydroammonium iodide.** C_{16}H_{36}IN. (M, 369.4). 1087900. [311-28-4].

**Content:** minimum 98.0 per cent of C_{16}H_{36}IN.

White or slightly coloured, crystalline powder or crystals, soluble in alcohol.

**Sulphated ash (2.4.14):** maximum 0.02 per cent.

**Assay.** Dissolve 1.200 g in 30 ml of water R. Add 50.0 ml of 0.1 M silver nitrate and 5 ml of dilute nitric acid R. Titrate the excess of silver nitrate with 0.1 M silver nitrate using 2 ml of ferric ammonium sulphate solution R2 as indicator.

1 ml of 0.1 M silver nitrate is equivalent to 36.94 mg of C_{16}H_{36}IN.

**Tetrachloroethane.** C_2H_2Cl_4. (M, 167.9). 1088000. [79-34-5]. 1,1,2,2-Tetrachloroethane.

A clear, colourless liquid, slightly soluble in water, miscible with alcohol. $d_20^0$: about 1.59.
**4.1.1. Reagents**

**Tetrachlorvinphos.** C₈H₆Cl₂O₄P. (M₂, 366.0). 1132500. [22248-79-9]. mp: about 95 °C. A suitable certified reference solution (10 ng/µl in iso-octane) may be used.


**Tetradecylammonium bromide.** C₄₀H₈₄BrN. (M₂, 659). 1116200. [22248-79-9]. White or almost white, crystalline powder. mp: about 100 °C.

**Tetradecane.** C₁₄H₃₀. (M₂, 198.4). 1088200. [629-59-4]. mp: 89 °C to 91 °C. A white or slightly coloured, crystalline powder or crystals.

**Tetrahexylammonium bromide.** C₂₈H₆₀BrN. (M₂, 434.6). 1152500. [4328-13-6]. White or almost white, crystalline powder or crystals. mp: about 95 °C.

**Tetraheptylammonium bromide.** C₃₀H₆₂BrN. (M₂, 434.6). 1152500. [4328-13-6]. White or almost white, crystalline powder or crystals. mp: about 100 °C.

**Tetrahydrofuran.** C₄H₈O. (M₂, 72.1). 1088500. [109-99-9]. A clear, colourless, flammable liquid, miscible with water, with alcohol.

**Tetrahydrofuran for chromatography R.** 1147100. It complies with the requirements of tetrahydrofuran R and with the following requirements:

- Minimum transmittance 2.2.25, determined using water R as compensation liquid: 20 per cent at 255 nm, 80 per cent at 270 nm, 98 per cent at 310 nm.

**Tetrahydrofuran for spectrophotometry complies with the following additional requirement.**

Minimum transmittance (2.2.25), determined using water R as compensation liquid: 20 per cent at 255 nm, 80 per cent at 270 nm, 98 per cent at 310 nm.

**Tetrahydrofuran for chromatography R.** 1147100. It complies with the requirements of tetrahydrofuran R and with the following requirements:

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**Tetrahydrofuran for spectrophotometry complies with the following additional requirement.**

Minimum transmittance (2.2.25), determined using water R as compensation liquid: 20 per cent at 255 nm, 80 per cent at 270 nm, 98 per cent at 310 nm.
Tetramethylethylenediamine. \( \text{C}_6\text{H}_{14}\text{N}_2 \) (\( M_r 114.1500 \)). [54827-17-7]. 3.3,5.5-Tetramethylbibenzyle-4,4’-diamine. A powder, practically insoluble in water, very slightly soluble in methanol.

mp: about 169 °C.

1,1,3,3-Tetramethylbutylamine. \( \text{C}_8\text{H}_{19}\text{N} \) (\( M_r 113.2600 \)). [107-45-9]. 2-Amino-2,4,4-trimethylpentane. A clear, colourless liquid.

mp: about 90 °C.

Tetramethyldiaminodiphenylmethane. \( \text{C}_{16}\text{H}_{20}\text{N}_2 \) (\( M_r 254.4 \)). \[101-61-1\]. 4,4′-Dimethyl-2,2′-diphenyltetrazolium bromide. MTT.

Theobromine. \( \text{C}_{17}\text{H}_{22}\text{N}_2 \) (\( M_r 254.4 \)). \[132-69-2\]. 1,3,7-Tetramethyluric-4-one. mp: about 159 °C.

mp: about 193 °C.

Chromatography (2.2.27). Examine as prescribed in identification test B in the monograph on Raw opium (0777), applying to the plate as a band (20 mm x 3 mm) 20 μl of a 0.5 g/l solution. The chromatogram obtained shows an orange-red or red principal band with an \( R_f \) of about 0.5.

Theobromine. \[113-88-0\]. 83-67-0.

See Theobromine (0298).


See Theophylline (0299).

Thiazamole. \( \text{C}_{4}\text{H}_{8}\text{N}_2\text{S} \) (\( M_r 114.2 \)). \[1089-400\]. 60-56-0.

Methimazole. 1-Methyl-1H-imidazole-2-thiol.

A white or almost white, amorphous powder, freely soluble in water, in alcohol and in acetone.

A 40 g/l solution.

Thioacetamide reagent. \[1089-600\]. 62-55-5.

A crystalline powder, slightly soluble in water and in alcohol.

mp: about 65 °C.

Thioacetamide. \( \text{C}_4\text{H}_8\text{NS} \) (\( M_r 75.1 \)). \[1089-600\]. 62-55-5.

A crystalline powder, slightly soluble in water and in alcohol.

mp: about 113 °C.

Thioacetamide. \( \text{C}_4\text{H}_8\text{NS} \) (\( M_r 75.1 \)). \[1089-600\]. 62-55-5.

A crystalline powder, slightly soluble in water and in alcohol.

mp: about 113 °C.

Thioacetamide reagent. \[1089-600\].

To 0.2 ml of thioacetamide solution R add 1 ml of a mixture of 5 ml of water R, 15 ml of \( 1 \text{M sodium hydroxide} \) and 20 ml of glycerol (85 per cent) R. Heat in a water-bath for 20 s. Prepare immediately before use.

Thioacetamide solution. \[1089-602\].

A 40 g/l solution.

Thiobarbituric acid. \( \text{C}_6\text{H}_5\text{N}_2\text{O}_3 \) (\( M_r 144.2 \)). \[1112-200\]. 504-17-6.

4,6-Dihydroxy-2-sulfanylpyrimidine.
4.1.1. Reagents

**Thiodiethylene glycol.** C₈H₁₄O₃. (M, 122.2). 1122900. [111-48-8]. Di(2-hydroxyethyl) sulphide. A colourless or yellow, viscous liquid. It contains at least 99.0 per cent of C₈H₁₄O₃. d₂₀° about 1.18.


**Thiolic acid.** C₂H₄O₂S. (M, 76.1). 1089900. [62-56-6]. White or almost white, crystalline powder or crystals, soluble in water and in alcohol. mp: about 178 °C.

**Threonine.** 1090000. [72-19-5]. See Threonine (1049).

**Thrombin, bovine.** 1090200. [9002-04-4]. A preparation of the enzyme, obtained from bovine plasma, that converts fibrinogen into fibrin.

**Thrombin, human.** 1090100. [9002-04-4]. Dried human thrombin. A preparation of the enzyme which converts human fibrinogen into fibrin. It is obtained from liquid human plasma and may be prepared by precipitation with suitable salts and organic solvents under controlled conditions of pH, ionic strength and temperature. A yellowish-white powder, freely soluble in water, soluble in alcohol. mp: 150 °C to 152 °C.

**Thioursa.** CH₅N₅S. (M, 76.1). 1090000. [72-19-5]. 2-

**Thrombin solution, human.** 1090101. Reconstitute human thrombin R as directed by the manufacturer and dilute with trishydroxymethylaminomethane sodium chloride buffer solution pH 7.4 R to 5 IU/ml.

**Thrombin solution, human R1.** 1090102. Reconstitute human thrombin R as directed by the manufacturer and dilute to 2.5 IU/ml with phosphate buffer solution pH 6.5 R.

**Thromboplastin.** 1090300. Extract 1.5 g of acetone-dried ox brain R with 60 ml of water R at 50 °C for 10 min to 15 min, centrifuge at 1500 r/min for 2 min and decant the supernatant liquid. The extract retains its activity for several days when stored in a refrigerator. It may contain 3 g/l of cresol R as an antimicrobial preservative.

**Thujone.** C₁₀H₁₆O. (M, 152.2). 1116500. [76231-76-0]. 4-Methyl-1-(1-methyl-1-bicyclo[3.1.0]hexan-3-one. A colourless or almost colourless liquid, practically insoluble in water, soluble in alcohol and in many other organic solvents.

**Thymidine.** C₁₀H₁₄N₅O₅. (M, 242.2). 1158900. 1-(2-Deoxy-beta-D-erythro-pentofuranosyl)-5-methylpyrimidine-2,4(1H,3H)-dione. Needles, soluble in water, in hot ethanol (96 per cent) and in glacial acetic acid.

**Thymine.** C₆H₅N₅O₅. (M, 126.1). 1090400. [65-71-4]. 5-Methylpyrimidine-2,4(1H,3H)-dione. Short needles or plates, slightly soluble in cold water, soluble in hot water. It dissolves in dilute solution of alkali hydroxides.

**Thymol.** 1090500. [89-83-8]. See Thymol (0791).

**Thymol used in gas chromatography complies with the following additional test.**

**Assay.** Examine by gas chromatography (2.2.28) as prescribed in the monograph Peppermint oil (0405).

**Test solution.** Dissolve 0.1 g in about 10 ml of acetone R.

The area of the principal peak is not less than 95.0 per cent of the area of all the peaks in the chromatogram obtained. Disregard the peak due to acetone.


**Thymol blue solution.** 1090601. Dissolve 0.1 g of thymol blue R in a mixture of 2.15 ml of 0.1 M sodium hydroxide and 20 ml of alcohol R and dilute to 100 ml with water R. Test for sensitivity. To 0.1 ml of the thymol blue solution add 100 ml of carbon dioxide-free water R and 0.2 ml of 0.02 M sodium hydroxide. The solution is blue. Not more than 0.15 ml of 0.02 M hydrochloric acid is required to change the colour to yellow.

**Colour change:** pH 1.2 (red) to pH 2.8 (yellow); pH 8.0 (olive-green) to pH 9.6 (blue).

**Thymolphthalein.** C₁₂H₁₀N₄O₆ (M, 430.5). 1090700. [125-20-2]. 3,3-bis(4-Hydroxy-5-isopropyl-2-methylphenyl)-3-(3-isobenzo-furan-1-one. A white or yellowish-white powder, practically insoluble in water, soluble in alcohol and in dilute solutions of alkali hydroxides.

**Thymolphthalein solution.** 1090701. A 1 g/1 solution in alcohol R.

**Test for sensitivity.** To 0.2 ml of the thymolphthalein solution add 100 ml of carbon dioxide-free water R. The solution is colourless. Not more than 0.05 ml of 0.1 M sodium hydroxide is required to change the colour to blue.

**Colour change:** pH 9.3 (colourless) to pH 10.5 (blue).

**Tin.** Sn. (4, 118.7). 1090800. [7440-31-5]. Silvery-white granules, soluble in hydrochloric acid with release of hydrogen. Arsenic (2.4.2). 0.1 g complies with limit test A (10 ppm).

Titanium. \( \text{Ti} \) (7440-32-6). A yellowish-brown powder, freely soluble in water and in alcohol.

**Titanium dioxide.** 1117900. [13463-67-7].

*Content:* minimum 99 per cent of Ti.

*mp:* about 1668 °C.

*Density:* about 4.507 g/cm³.

**Titanium trichloride.** 1091200. [7705-07-9]. Titanium(III) chloride.

Reddish-violet crystals, deliquescent, soluble in water and in alcohol.

*mp:* about 440 °C.

**Titanium trichloride solution.** 1091201.

*\( \text{d}_{20}^m \):* about 1.19.

A 150 g/l solution in hydrochloric acid (100 g/l HCl).

**Titanium trichloride-sulphuric acid reagent.** 1091202.

Carefully mix 20 ml of titanium trichloride solution \( R \) with 13 ml of sulphuric acid \( R \). Add sufficient strong hydrogen peroxide solution \( R \) to give a yellow colour.

Heat until white fumes are evolved. Allow to cool. Dilute with \( \text{water} \) \( R \) and repeat the evaporation and addition of \( \text{water} \) \( R \) until a colourless solution is obtained. Dilute to 100 ml with \( \text{water} \) \( R \).

**TLC aluminium oxide G plate.** 1165200.

Support of metal, glass or plastic, coated with a layer of aluminium oxide (particle size 5-40 µm) containing about 10 per cent of calcium sulphate hemihydrate as a binder.

**TLC octadecylsilyl silica gel plate.** 1148600.

Support of glass, metal or plastic coated with a layer of octadecylsilyl silica gel. The plate may contain an organic binder.

**TLC octadecylsilyl silica gel \( F_{254} \) plate \( R \).** 1146600.

Support of glass, metal or plastic coated with a layer of octadecylsilyl silica gel.

It contains a fluorescent indicator having a maximum absorbance in ultraviolet light at 254 nm.

**TLC performance test solution.** 1116600.

Prepare a mixture of 1.0 ml of each of the following solutions and dilute to 10.0 ml with acetone \( R \): a 0.5 g/l solution of Sudan red \( G \) in toluene \( R \), a 0.5 g/l solution of methyl orange \( R \) in ethanol \( R \) prepared immediately before use, a 0.5 g/l solution of bromocresol green \( R \) in acetone \( R \) and a 0.25 g/l solution of methyl red \( R \) in acetone \( R \).

**TLC silica gel plate.** 1116700.

Support of glass, metal or plastic, coated with a layer of silica gel of a suitable thickness and particle size (usually 2 µm to 10 µm for fine particle size (High Performance Thin-Layer Chromatography, HPTLC) plates and 5 µm to 40 µm for normal TLC plates). If necessary, the particle size is indicated after the name of the reagent in the tests where it is used.

The plate may contain an organic binder.

**Chromatographic separation.** Apply to the plate an appropriate volume (10 µl for a normal TLC plate and 1 µl to 2 µl for a fine particle size plate) of TLC performance test solution \( R \). Develop over a pathlength two-thirds of the plate height, using a mixture of 20 volumes of methanol \( R \) and 80 volumes of toluene \( R \). The plate is not satisfactory, unless the chromatogram shows four clearly separated spots, the spot of bromocresol green with an \( R_f \) value less than 0.15, the spot of methyl orange with an \( R_f \) value in the range of 0.1 to 0.25, the spot of methyl red with an \( R_f \) value in the range of 0.35 to 0.55 and the spot of Sudan red \( G \) with an \( R_f \) value in the range of 0.75 to 0.98.

**TLC silica gel \( F_{254} \) plate.** 1116800.

It complies with the requirements prescribed for TLC silica gel plate \( R \) with the following modification.

It contains a fluorescent indicator having a maximum absorbance at 254 nm.

**Fluorescence suppression.** Apply separately to the plate at five points increasing volumes (1 µl to 10 µl for normal TLC plates and 0.2 µl to 2 µl for fine particle size plates) of a 1 g/l solution of benzoic acid \( R \) in a mixture of 15 volumes of ethanol \( R \) and 85 volumes of cyclohexane \( R \). Develop over a pathlength half of the plate height with the same mixture of solvents. After evaporating the solvents examine the chromatogram in ultraviolet light at 254 nm. For normal TLC plates the benzoic acid appears as dark spots on a fluorescent background approximately in the middle of the chromatogram for quantities of 2 µg and greater. For fine particle size plates the benzoic acid appears as dark spots on a fluorescent background approximately in the middle of the chromatogram for quantities of 0.2 µg and greater.

**TLC silica gel \( F_{254} \) silanised plate.** 1117200.

It complies with the requirements prescribed for TLC silica gel silanised plate \( R \) with the following modification.

It contains a fluorescent indicator having a maximum absorbance at 254 nm.

**TLC silica gel \( G \) plate.** 1116900.

It complies with the requirements prescribed for TLC silica gel plate \( R \) with the following modification.

It contains calcium sulphate hemihydrate as binder.

**TLC silica gel \( GF_{254} \) plate.** 1117000.

It complies with the requirements prescribed for TLC silica gel plate \( R \) with the following modifications.

It contains calcium sulphate hemihydrate as binder and a fluorescent indicator having a maximum absorbance at 254 nm.

**Fluorescence suppression.** Complies with the test prescribed for TLC silica gel \( F_{254} \) plate \( R \).
4.1.1. Reagents

**TLC silica gel plate for chiral separations, octadecylsilyl.**

Support of glass, metal or plastic, coated with a layer of octadecylsilyl silica gel, impregnated with Cu²⁺ ions and enantiomerically pure hydroxyproline. The plate may contain an organic binder.

**TLC silica gel, silanised plate.**

Support of glass, metal or plastic, coated with a layer of silanised silica gel of a suitable thickness and particle size (usually 2 µm to 10 µm for fine particle size (High Performance Thin-Layer Chromatography, HPTLC) plates and 5 µm to 40 µm for normal TLC plates). If necessary, the particle size is indicated after the name of the reagent in the tests where it is used.

The plate may contain an organic binder.

**Chromatographic separation.** Introduce 0.1 g each of methyl laurate R, methyl myristate R, methyl palmitate R and methyl stearate R into a 250 ml conical flask. Add 40 ml of alcoholic potassium hydroxide solution R and heat under a reflux condenser on a water-bath for 1 h. Allow to cool, transfer the solution to a separating funnel by means of 100 ml of water R, acidify (pH 2 to 3) with dilute hydrochloric acid R and shake with three quantities each of 10 ml of methylene chloride R. Dry the combined methylene chloride extracts over potassium carbonate R and evaporate to dryness on a water-bath. Dissolve the residue in 50 ml of methylene chloride R. Examine by thin-layer chromatography (2.2.27), using silanised TLC silica gel plate R. Apply an appropriate quantity (about 10 µl) for normal TLC plates and about 1 µl to 2 µl for fine particle size plates) of the methylene chloride solution of each of three separate points. Develop over a pathlength two-thirds of the plate height with a mixture of 10 volumes of glacial acetic acid R, 25 volumes of water R and 65 volumes of dioxan R. Dry the plate at 120 °C for 30 min. Allow to cool, spray with a 35 g/l solution of phosphomolybdic acid R in 2-propanol R and heat at 150 °C until the spots become visible. Treat the plate with ammonia vapour until the background is white. The chromatograms show four clearly separated, well-defined spots.

α-Tocopherol. 1152300. [1091-41-0].

See all-rac-α-Tocopherol (0692).

α-Tocopheryl acetate. 1152400. [7695-91-2].

See all-rac-α-Tocopheryl acetate (0439).

**α-Toluidine.** C₇H₅NO₂. (M₁, 112.1). 1123000. [119-93-7]. 3,3’-Dimethylbenzidine.

Content: minimum 97.0 per cent of C₇H₅NO₂.

A light brownish, crystalline powder.

mp: about 130 °C.

**α-Toluidine solution.** 1123001.

Dissolve 0.16 g of α-toluidine R in 30.0 ml of glacial acetic acid R, add 1.0 g of potassium iodide R and dilute to 500.0 ml with water R.

**Toluene.** C₇H₈. (M₁, 92.1). 1091300. [108-88-3].

Methylbenzene.

A clear, colourless, flammable liquid, very slightly soluble in water, miscible with alcohol.

ρ₂⁰: 0.855 to 0.870.

bp: about 110 °C.

**Toluene, sulphur-free.** 1091301.

Complies with the requirements prescribed for toluene R and with the following additional requirements:

* Sulphur compounds.* To 10 ml add 1 ml of ethanol R and 3 ml of potassium plumbite solution R and boil under a reflux condenser for 15 min. Allow to stand for 5 min. No darkening is produced in the aqueous layer.

* Thiophen-related substances.* Shake 2 ml with 5 ml of isatin reagent R for 5 min and allow to stand for 15 min. No blue colour is produced in the lower layer.

**Toluenesulphonamide.** C₇H₅NO₃S, (M₁, 171.2). 1091400. [88-19-7]. 2-Methylbenzenesulphonamide.

A white or almost white, crystalline powder, slightly soluble in water, soluble in alcohol and in solutions of alkali hydroxides.

mp: about 136 °C.

**Chromatography.** Examine as prescribed in the monograph on Tolubutamide (0304); the chromatogram shows only one principal spot.


A white or almost white, crystalline powder, slightly soluble in water, soluble in alcohol and in solutions of alkali hydroxides.

mp: about 156 °C.

**p-Toluenesulphonamide.** 1091500. [70-55-3].

See toluenesulphonamide R.

**Toluenesulphonic acid.** C₇H₅O₃S·H₂O, (M₁, 190.2). 1091600. [6192-52-5]. 4-Methylbenzenesulphonic acid.

Content: minimum 87.0 per cent of C₇H₅O₃S.

A white or almost white, crystalline powder or crystals, freely soluble in water, soluble in alcohol.

**α-Toluidine.** C₇H₅N. (M₁, 107.2). 1091700. [95-53-4]. 2-Methylaniline.

A pale-yellow liquid becoming reddish-brown on exposure to air and light, slightly soluble in water, soluble in alcohol and in dilute acids.

ρ₂⁰: about 1.01.

η₂⁰: about 1.569.

bp: about 200 °C.

Storage: in an airtight container, protected from light.

**α-Toluidine hydrochloride.** C₇H₅ClN·HCl, (M₁, 143.6). 1117300. [636-21-5]. 2-Methylaniline hydrochloride. 2-Methylbenzenamine hydrochloride.

Content: minimum 98.0 per cent of C₇H₅ClN.

mp: 215 °C to 217 °C.

**p-Toluidine.** C₇H₅N, (M₁, 107.2). 1091800. [106-49-0]. 4-Methylaniline.

Lustrous plates or flakes, slightly soluble in water, freely soluble in acetone and in alcohol.

mp: about 44 °C.

**Toluidine blue.** C₁₃H₁₃ClN₂S₂. (M₁, 305.8). 1091900. [92-31-9].

Schultz No. 1041.

Colour Index No. 52040.
Toluidine Blue O. 3-Amino-7-dimethylamino-2-methylphenothiazin-5-ium chloride.
A dark-green powder, soluble in water, slightly soluble in alcohol.

Tosylarginine methyl ester hydrochloride.
C$_{14}$H$_{23}$ClN$_4$O$_4$S. ([76-03-9]).
N-Tosyl-L-arginine methyl ester hydrochloride. Methyl (S)-5-guanidino-2-(4-methylbenzenesulphonamido)valerate hydrochloride.

$[\alpha]_D^{20}$: +7 to +9, determined on a 20 g/l solution.
mp: about 155 °C.

Tosylarginine methyl ester hydrochloride solution.
1092000.
To 98.5 mg of tosylarginine methyl ester hydrochloride R add 3 ml of tris(hydroxymethyl)aminomethane buffer solution pH 8.1 R and shake to dissolve. Add 2.5 ml of methanol red mixture R solution and dilute to 25.0 ml with water.

Tosyl-lysyl-chloromethane hydrochloride.
C$_{14}$H$_{22}$Cl$_2$N$_2$O$_3$S. ([8001-35-2]).
(N-Tosyl-L-lysyl-chloromethane hydrochloride. (3S)-7-Aminooctadeca-4,7,10,13,16,19-hexaenoyl-L-lysylchloromethane.)

A dark-green powder, soluble in water, slightly soluble in alcohol.

A suitable certified reference solution (10 ng/µl in iso-octane)
mp : 65° C to 90° C.
A mixture of polychloro derivatives.

A suitable certified reference solution (10 ng/µl in iso-octane)
may be used.

Ttragacanth. 1092300. [9000-65-1].
See Tragacanth (0532).

Triacetin. C$_3$H$_6$O$_3$. ([218.2]). 1092400. [102-76-1].
Propane-1,2,3-triyl triacetate. Glycerol triacetate.
An almost clear, colourless to yellowish liquid, soluble in water, miscible with alcohol.

$\delta_2^20$: about 1.043.
$\eta_2^20$: about 1.445.

Trichloethylene. 1102100.
See Trichloethylene R.

Trichloroacetic acid. C$_3$HCl$_3$O$_2$. (M, 163.4). 1092500. [76-03-9].
Colourless crystals or a crystalline mass, very deliquescent, very soluble in water and in alcohol.

Storage: in an airtight container.

Trichloroacetic acid solution. 1092501.
Dissolve 40.0 g of trichloroacetic acid R in water R and dilute to 1000.0 ml with the same solvent. Verify the concentration by titration with 0.1 M sodium hydroxide and adjust if necessary to 40 ± 1 g/l.

1,1,2-Trichloroethane. C$_3$HCl$_3$O. (M, 133.4). 1092600. [71-55-6].
Methylchloroform.
A non-flammable liquid, practically insoluble in water, soluble in acetone and in methanol.

$\delta_2^20$: about 1.34.
$\eta_2^20$: about 1.438.
bp: about 74 °C.

Trichloroethylene. C$_3$HCl$_3$ (M, 131.4). 1102100. [79-01-6].
A colourless liquid, practically insoluble in water, miscible with alcohol.

$\delta_2^20$: about 1.46.
$\eta_2^20$: about 1.477.

1,1,2-Trichloro-1,2,2-trifluoroethane.
A colourless, volatile liquid, practically insoluble in water, miscible with acetone.

$\delta_2^20$: about 1.58.
Distillation range (2.2.11). Not less than 98 per cent distils between 47 °C and 48 °C.

Tricine. C$_6$H$_{13}$NO$_5$. (M, 179.2). 1138900. [5704-04-1].
$\eta_2$[2-Hydroxy-1,1-bis(hydroxymethyl)ethyl]glycine.
Use electrophoresis-grade reagent.
mp: about 183 °C.

Triethanolamine. C$_6$H$_{15}$N. ([102-71-6]). 1144900. [638-67-5].
White or almost white crystals, practically insoluble in water, soluble in hexane.

mp: about 48 °C.

Tridocosahexaenoin. C$_{23}$H$_{48}$. (M, 324.6). 1092800. [124596-98-1].
Triglyceride of docosahexaenoic acid (C22:6). Glycerol tridocosahexaenoate. Propane-1,2,3-triyl tri(all-2Z)-docosa-4,7,10,13,16,19-hexaenoate.
The reagent from Nu-Chek Prep, Inc. has been found suitable.

Triethanolamine. 1092900. [102-71-6].
See Trolamine (1577).

Triethylamine. C$_6$H$_{13}$N. (M, 101.2). 1093000. [121-44-8].
N,N-Diethylthlamine.
A colourless liquid, slightly soluble in water at a temperature below 18.7 °C, miscible with alcohol.

$\delta_2^20$: about 0.727.
$\eta_2^20$: about 1.27.
bp: about 79 °C.
Trieglubilline hydrochloride. C7H8ClNO2. (mp: about 46 °C. White or light yellow, crystalline solid or powder. [402-45-9].


See the information section on general monographs (cover pages).

4.1.1. Reagents

EUROPEAN PHARMACOPOEIA 6.0

Trimethylpentane R1. 1093401.

Complies with the requirements prescribed for trimethylpentane R with the following additional requirements. 

Absorbance (2.2.25). Not more than 0.07 from 220 nm to 360 nm, determined using water R as the compensation liquid.

N,O-bis(Trimethylsilyl)acetamide. C8H17NOSi2- (M, 203.4). 1093600. [10416-59-8].

Colourless liquid. d20⁰: about 0.83.

N-Trimethylsilylimidazole. C5H13NSi (M, 140.3). 1100500. [18156-74-6]. 1-Trimethylsilylimidazole.

A colourless, hygroscopic liquid. d20⁰: about 0.96. nD20: about 1.48. 

Storage: in an airtight container.

N,O-bis(Trimethylsilyl)trifluoroacetamide. C11H15NOSi2- (M, 257.4). 1133200. [25561-30-2]. BSTFA.

Colourless liquid. d20⁰: about 0.97. nD20: about 1.38. bp12mm: about 40 °C

Trimethylsulphonium hydroxide. C3H10OS. (bp12mm: about 72 °C.

Liquid, miscible with acetone and with alcohol. 

Storage: in an airtight container.

Triethylamine R1.

Use freshly distilled or from a freshly opened container.

Triethylamine R1.

Water 1. Not more than 0.1 per cent.

Storage: protected from light.
**Triphenyltetrazolium chloride solution.** 1093801. A 5 g/1 solution in aldehyde-free alcohol R. 
**Storage:** protected from light.

**Tris[2,4-di(1,1-dimethylethyl)phenyl] phosphite.** C42H63O3P. (M, 2094.1). 
A viscous, brown-yellow liquid, soluble in methanol. Used as a stationary phase in gas chromatography. 
**Viscosity (2.2.9):** about 172 mPas. 
**mp:** 218 °C to 222 °C. 

**Tri(hydroxymethyl)aminomethane.** C33H42O19. (M, 380.2). Troxerutin. 
Colourless or white or almost white crystals, freely soluble in water. 
**mp:** 168 °C to 176 °C. 

**Trypsin.** 
A proteolytic enzyme obtained by activation of trypsinogen extracted from the pancreas of beef (Bos taurus L.). 
A white or almost white, crystalline or amorphous powder, sparingly soluble in water. 
**mp:** about 115 °C. 
**bp:** about 110 °C. 
**Assay:** determined by method 1094700. 
**Storage:** protect from light.

**Trypsin for peptide mapping.** 1094600. 
Trypsin of high purity treated to eliminate chymotryptic activity.

**Tryptophan.** C11H12N2O2. (M, 204.2). 1094700. 
A white or yellowish-white, crystalline powder or colourless crystals, slightly soluble in water, very slightly soluble in alcohol. 
**d20 :** about 0.981. 
**nD20 :** about 1.508. 
**bp:** about 123 °C. 
**Valencene used in gas chromatography complies with the following additional test.** 
**Assay:** Examine by gas chromatography (2.2.28) as prescribed in the monograph on Sweet orange oil (1811). The content is not less than 80 per cent, calculated by the normalisation procedure.

**Valerene.** C13H12O2. (M, 234.3). 1165700. 
**Valeric acid.** C4H8O2. (M, 102.1). 1095200. 
**Pentanoic acid.** 
A colourless liquid, soluble in water, freely soluble in alcohol. 
**d20 :** about 0.94. 
**nD20 :** about 1.409. 
**bp:** about 186 °C.
Vanillin. 1095300. [121-33-5].
See Vanillin (0747).

Vanillin reagent. 1095301.
Carefully add, dropwise, 2 ml of sulphuric acid R to 100 ml of a 10 g/l solution of vanillin in alcohol R.
Storage: use within 48 h.

Vanillin solution, phosphoric. 1095302.
Dissolve 1.0 g of vanillin in 25 ml of alcohol R. Add 25 ml of water R and 35 ml of phosphoric acid R.

Veratrole. \( \text{C}_6\text{H}_9\text{NO} \). (M, 138.2). 1165400. [91-16-7].
1,2-Dimethoxybenzene.

Verbenone. \( \text{C}_{10}\text{H}_{14}\text{O} \). (M, 150.2).

Vinyl acetate. \( \text{C}_2\text{H}_3\text{Cl} \). (M, 86.1). 1095400. [75-01-4].
A colourless gas, slightly soluble in organic solvents.

Vinyl chloride. \( \text{C}_2\text{H}_3\text{Cl} \). (M, 62.5). 1095400. [75-01-4].
A colourless gas, slightly soluble in organic solvents.

Vinyl polymer for chromatography, octadecyl. 1155400.
Spherical particles (5 µm) of a vinyl alcohol copolymer chemically modified by bonding of octadecyl groups on the hydroxyl groups.

Vinyl polymer for chromatography, octadecylsilyl. 1121600.
Spherical particles (5 µm) of a vinyl alcohol copolymer bonded to an octadecylsilyl. Carbon content of 17 per cent.

2-Vinylpyridine. \( \text{C}_7\text{H}_7\text{N} \). (M, 105.1). 1102200. [100-69-6].
A yellow liquid, miscible in water.

1-Vinylpyrrolidin-2-one. \( \text{C}_8\text{H}_{10}\text{O}_2 \). (M, 111.1). 1111900. [88-12-0].

Assay. Examine by gas chromatography (2.2.28).
The chromatography may be carried out using
- a fused-silica column 30 m long and 0.5 mm in internal diameter the inner wall of which is coated with a 1.0 µm layer of macrogol 20 000 R,
- helium for chromatography R as the carrier gas,
- a flame-ionisation detector,

maintaining the temperature of the injection port at 190 °C and programming the temperature of the column as follows: maintain the temperature at 80 °C for 1 min and then increase it to 190 °C at a rate of 10 °C per minute. Maintain at 190 °C for 15 min. Inject 0.5 µl of the substance to be examined and adjust the flow rate of the carrier gas so that the retention time of the peak corresponding to 1-vinylpyrrolidin-2-one is about 17 min. Determine the content of \( \text{C}_8\text{H}_{10}\text{O}_2 \) by internal normalisation.

Vitexin. \( \text{C}_{21}\text{H}_{20}\text{O}_{10} \). (M, 448.4).
Apigenin 8-glucoside.
Yellow powder.
Storage: in an airtight container, protected from light.

Water. 1095500. [7732-18-5].
See Purified water (0008).

Water R1. 1095509.
Prepared from distilled water R by multiple distillation. Remove carbon dioxide by boiling for at least 15 min before use in a boiling flask of fused silica or borosilicate glass and cool. Any other suitable method may be used. The boiling flask has been already used for the test or has been filled with water R and kept in an autoclave at 121 °C for at least 1 h prior to first use. When tested immediately before use, water R1 is neutral to methyl red solution R, i.e. it shall produce an orange-red (not a violet-red or yellow) colour corresponding to pH 3.5 ± 0.1 when 0.05 ml of methyl red solution R is added to 50 ml of the water to be examined.

Conductivity: maximum 1 µS cm\(^{-1}\), determined at 25 °C by an in-line conductivity meter (see Purified water (0008)).

Water, ammonium-free. 1095501. [7732-18-5].
To 100 ml of water R add 0.1 ml of sulphuric acid R. Distil using the apparatus described for the determination of Distillation range (2.2.11). Reject the first 10 ml and collect the following 50 ml.

Water, carbon dioxide-free. 1095502. [7732-18-5].
Water R which has been boiled for a few minutes and protected from the atmosphere during cooling and storage.

Water for chromatography. 1095503. [7732-18-5].
Deionised water R with a resistivity of not less than 0.18 Mohm.m.

Water, distilled. 1095504. [7732-18-5].
Water R prepared by distillation.

Water, distilled, deionised. 1095508.
Deionised water R prepared by distillation with a resistivity of not less than 18 Mohm.m.

Water for injections. 1095505. [7732-18-5].
See Water for injections (0169).
Water, nitrate-free. 1095506. [7732-18-5].
To 100 ml of water R add a few milligrams of potassium permanganate R and of barium hydroxide R. Distil using the apparatus described for the determination of Distillation range (2.2.11). Reject the first 10 ml and collect the following 50 ml.

Water, particle-free. 1095507. [7732-18-5].
Filter water R through a membrane with a pore size of 0.22 µm.

Weak cationic resin. 1096000.
Polymeric resin, slightly acid, with carboxyl groups present in a protonated form.
Particle size: 75 µm to 160 µm.
PH limits of use: 5 to 14.
Maximum temperature of use: 120 °C.


Content: minimum 90.0 per cent of C13H10O2.
A white to pale-yellow powder, very slightly soluble in water, soluble in alcohol and in glacial acetic acid.

It is also available as a methanolic solution containing 90 g/l to 110 g/l of xanthylol.

mp: about 123 °C.

Assay. In a 250 ml flask dissolve 0.300 g in 3 ml of methanol R or use 3.0 ml of solution. Add 50 ml of glacial acetic acid R and, with shaking, 25 ml of a 20 g/l solution of urea R. Allow to stand for 12 h, collect the precipitate on a sintered-glass filter (16) (2.1.2), wash with 20 ml of alcohol R, dry in an oven at 100 °C to 105 °C and weigh.

1 g of precipitate is equivalent to 0.9429 g of xanthylol.

Storage: protected from light. If a methanolic solution is used, store in small sealed ampoules and filter before use if necessary.

Xanthylol R1. 1096101.
Complies with the requirements prescribed for xanthylol R and with the following requirement.

Content: minimum 98.0 per cent of C13H10O2.

Xanthylol solution. 1096102.
To 0.1 ml of a 100 g/l solution of xanthylol R in methanol R add 100 ml of glacial acetic acid R and 1 ml of hydrochloric acid R. Allow to stand for 24 h before using.

Xylene. C8H10. (M, 106.2). 1096200. [1330-20-7].
Mix of isomers. A clear, colourless, flammable liquid, practically insoluble in water, miscible with alcohol.

d30 : about 0.867.
ρD : about 1.497.
bp: about 138 °C.

m-Xylene. C8H10. (M, 106.2). 1117700. [108-38-3].
1,3-Dimethylbenzene.
A clear, colourless, flammable liquid, practically insoluble in water, miscible with alcohol.

d30 : about 0.884.
ρD : about 1.497.
bp: about 139 °C.
mp: about – 47 °C.

o-Xylene. C8H10. (M, 106.2). 1100600. [95-47-6].
1,2-Dimethylbenzene.
A clear, colourless, flammable liquid, practically insoluble in water, miscible with alcohol.

d30 : about 0.881.
ρD : about 1.505.
bp: about 144 °C.
mp: about – 25 °C.

Xylenol orange. C13H10N4O2S. (M, 261). 1096930. [3618-43-7].
Tetrasodium 3,3-(3H-2,1-benzoxathiol-3-ylidene)bis[6-hydroxy-5-methyl-3-phenylene)methyleneiminobisacetate] S2O4.
A reddish-brown crystalline powder, soluble in water.

Xylenol orange trinitrurate. 1096301.
Triturate 1 part of xylenol orange R with 99 parts of potassium nitrate R.
Test for sensitivity. To 50 ml of water R add 1 ml of dilute acetic acid R, 50 mg of the xylenol orange trinitrurate and 0.05 ml of lead nitrate solution R. Add hexamethylenetetramine R until the colour changes from yellow to violet-red. After addition of 0.1 ml of 0.1 M sodium edetate the colour changes to yellow.

Xylose. 1096400. [58-86-6].
See Xylose (1278).

Zinc, Zn. (A, 65.4). 1096500. [7440-66-6].

Content: minimum 99.5 per cent of Zn.
Silver-white cylinders, granules, pellets or filings with a blue sheen.

Arsenic (2.4.2). 5.0 g complies with limit test A (0.2 ppm). Dissolve in a mixture of the 15 ml of hydrochloric acid R and 25 ml of water R prescribed.

Zinc, activated. 1096501.
Place the zinc cylinders or pellets to be activated in a conical flask and add a sufficient quantity of a 50 ppm solution of chloroplatinic acid R to cover the metal. Allow the metal to remain in contact with the solution for 10 min, wash, drain and dry immediately.

Arsenic. To 5 g of the activated zinc add 15 ml of hydrochloric acid R, 25 ml of water R, 0.1 ml of stannous chloride solution R and 5 ml of potassium iodide solution R. Treat as described in limit test A for arsenic (2.4.2). No stain is produced on the mercuric bromide paper R.

Activity. Repeat the test for arsenic using the same reagents and adding a solution containing 1 µg of arsenic. An appreciable stain appears on the mercuric bromide paper R.

Zinc acetate. (C2H3O2)2Zn,2H2O. (M, 219.5). 1102300. [5970-45-6].
Zinc acetate dihydrate.

Mix 600 ml of water R with 150 ml of glacial acetic acid R, 54.9 g of zinc acetate R and stir to dissolve. Continue stirring while adding 150 ml of concentrated ammonia R. Cool to room temperature and adjust with ammonia R to pH 6.4. Dilute the mixture to 1 litre with water R.
4.1.2. Standard solutions for limit tests

Zinc chloride. 1096600.  [7646-85-7].
See Zinc chloride (0110).

**Zinc chloride-formic acid solution. 1096601.**
Dissolve 20 g of zinc chloride R in 80 g of an 850 g/l solution of anhydrous formic acid R.

**Zinc chloride solution, iodinated. 1096602.**
Dissolve 20 g of zinc chloride R and 6.5 g of potassium iodide R in 10.5 ml of water R. Add 0.5 g of iodine R and shake for 15 min. Filter if necessary.

*Storage:* protected from light.

**Zinc iodide and starch solution. 1096502.**
To a solution of 2 g of zinc chloride R in 10 ml of water R add 0.4 g of soluble starch R and heat until the starch has dissolved. After cooling to room temperature add 1.0 ml of a colourless solution containing 0.10 g zinc R as filings and 0.2 g of iodine R in water R. Dilute the solution to 100 ml with water R and filter.

*Storage:* protected from light.

**Test for sensitivity.** Dilute 0.05 ml of sodium nitrite solution R to 50 ml with water R. To 5 ml of this solution add 0.1 ml of dilute sulphuric acid R and 0.05 ml of the zinc iodide and starch solution and mix. The solution becomes blue.

**Zinc oxide. 1096700. [1314-13-2].**
See Zinc oxide (0252).

*Content:* minimum 99.0 per cent of Zn (A6, 65-A).
A very fine, grey powder, soluble in dilute hydrochloric acid R.

**Zinc sulphate. 1097000. [7446-20-0].**
See Zinc sulphate (0111).

**Zirconyl chloride.** A basic salt corresponding approximately to the formula ZrCl\(_2\)O,8H\(_2\)O. 1097100. [15461-27-5].
*Content:* minimum 96.0 per cent of ZrCl\(_2\)O,8H\(_2\)O.
White or almost white, crystalline powder or crystals, freely soluble in water and in alcohol.

*Assay.* Dissolve 0.600 g in a mixture of 5 ml of nitric acid R and 50 ml of water R. Add 50.0 ml of 0.1 M silver nitrate and 3 ml of dibutyl phthalate R and shake. Using 2 ml of ferric ammonium sulphate solution R2 as indicator, titrate with 0.1 M ammonium thiocyanate until a reddish-yellow colour is obtained.

1 ml of 0.1 M silver nitrate is equivalent to 16.11 mg of ZrCl\(_2\)O,8H\(_2\)O.

**Zirconyl nitrate.** A basic salt corresponding approximately to the formula ZrO(NO\(_3\))\(_2\),2H\(_2\)O. 1097200. [14985-18-3].
A white or almost white powder or crystals, hygroscopic, soluble in water. The aqueous solution is a clear or at most slightly opalescent liquid.

*Storage:* in an airtight container.

**Zirconyl nitrate solution. 1097201.**
A 1 g/l solution in a mixture of 40 ml of water R and 60 ml of hydrochloric acid R.

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4.1.2. STANDARD SOLUTIONS FOR LIMIT TESTS

Acetaldehyde standard solution (100 ppm C\(_2\)H\(_4\)O). 5000100.
Dissolve 1.0 g of acetaldehyde R in 2-propanol R and dilute to 100.0 ml with the same solvent. Dilute 5.0 ml of the solution to 500.0 ml with 2-propanol R. Prepare immediately before use.

Acetaldehyde standard solution (100 ppm C\(_2\)H\(_4\)O) R1. 5000101.
Dissolve 1.0 g of acetaldehyde R in water R and dilute to 100.0 ml with the same solvent. Dilute 5.0 ml of the solution to 500.0 ml with water R. Prepare immediately before use.

Aluminium standard solution (200 ppm Al). 5000200.
Dissolve in water R a quantity of aluminium potassium sulphate R equivalent to 0.352 g of AlK(SO\(_4\))\(_2\)·12H\(_2\)O. Add 10 ml of dilute sulphuric acid R and dilute to 100.0 ml with water R.

Aluminium standard solution (100 ppm Al). 5000203.
Immediately before use, dilute with water R to 10 times its volume a solution containing 8.947 g of aluminium chloride R in 1000.0 ml of water R.

Aluminium standard solution (10 ppm Al). 5000201.
Immediately before use, dilute with water R to 100 times its volume in a solution containing aluminium nitrate R equivalent to 1.39 g of Al(NO\(_3\))\(_3\)·9H\(_2\)O in 100.0 ml.

Aluminium standard solution (2 ppm Al). 5000202.
Immediately before use, dilute with water R to 100 times its volume a solution containing aluminium potassium sulphate R equivalent to 0.352 g of AlK(SO\(_4\))\(_2\)·12H\(_2\)O and 10 ml of dilute sulphuric acid R in 100.0 ml.

Ammonium standard solution (100 ppm NH\(_3\)). 5000300.
Immediately before use, dilute to 25 ml with water R to 10 ml of a solution containing ammonium chloride R equivalent to 0.741 g of NH\(_4\)Cl in 1000 ml.

Ammonium standard solution (2.5 ppm NH\(_3\)). 5000301.
Immediately before use, dilute with water R to 100 times its volume a solution containing ammonium chloride R equivalent to 0.741 g of NH\(_4\)Cl in 1000.0 ml.

Ammonium standard solution (1 ppm NH\(_3\)). 5000302.
Immediately before use, dilute ammonium standard solution (2.5 ppm NH\(_3\)) R to 2.5 times its volume with water R.

Antimony standard solution (100 ppm Sb). 5000401.
Dissolve antimony potassium tartrate R equivalent to 0.274 g of C\(_6\)H\(_5\)KO\(_7\) Sb,\(_{1/2}\)H\(_2\)O in 500 ml of 1M hydrochloric acid R and dilute the clear solution to 1000 ml with water R.

Antimony standard solution (1 ppm Sb). 5000400.
Dissolve antimony potassium tartrate R equivalent to 0.274 g of C\(_6\)H\(_5\)KO\(_7\) Sb,\(_{1/2}\)H\(_2\)O in 20 ml of hydrochloric acid R1 and dilute the clear solution to 100.0 ml with water R. To 10.0 ml of this solution add 200 ml of hydrochloric acid R1 and dilute to 1000.0 ml with water R. To 100.0 ml of this solution add 300 ml of hydrochloric acid R1 and dilute to 1000.0 ml with water R. Prepare the dilute solutions immediately before use.