## B - Barium chloride (0.1 mol/L) VS.... Butylated hydroxytoluene R

***Barium chloride (0.1 mol/L) VS***

Barium chloride R, dissolved in water R to contain 20.8 g of $BaCl_2$ in 1000 mL.

*Method of standardization.* Ascertain the exact concentration of the solution by following the method described under barium chloride (0.5 mol/L) VS.

***Barium chloride (0.5 mol/L) VS***

Barium chloride R, dissolved in water to contain 104.2 g of $BaCl_2$ in 1000 mL.

*Method of standardization.* Ascertain the exact concentration of the 0.5 mol/L solution in the following manner: Place 10.0 mL of sulfuric acid (0.5 mol/L) VS in a flask, dilute with 40 mL of water, add 2 drops of thorin (2 g/L) TS and titrate slowly with the barium chloride solution to a reddish colour.

***Barium chloride (50 g/L) TS***

A solution of barium chloride R containing about 52 g/L of $BaCl_2$ (approximately 0.25 mol/L).

***Barium chloride (120 g/L) TS***

A solution of barium chloride R containing about 120 g of barium chloride per litre.

***Barium chloride R***

$BaCl_2,2H_2O$ (SRIP, 1963, p. 45).

***Barium hydroxide (0.15mol/L) VS***

Barium hydroxide R dissolved in carbon-dioxide-free water R to contain 25.7 g of $Ba(OH)_2$ in 1000 mL.

***Barium hydroxide (15 g/L)TS***

A solution of barium hydroxide R in carbon-dioxide-free water R containing about 15 g of $Ba(OH)_2$ per litre.

*Note:* Barium hydroxide (15 g/L) TS must be freshly prepared.

***Barium hydroxide R***

$Ba(OH)_2,8H_2O$ (SRIP, 1963, p. 46).

***Barium nitrate (0.01 mol/L) VS***

Barium nitrate R, dissolved in water to contain 2.614 g of $Ba(NO_3)_2$ in 1000 mL.

*Method of standardization.* Ascertain the exact concentration of the 0.01 mol/L solution in the following manner: Place 10.0 mL of sulfuric acid (0.01 mol/L) VS in a flask, dilute with 40 mL of water, add 2 drops of thorin (2 g/L) TS and 2 drops of methylthioninium chloride (0.2 g/L) TS and titrate slowly with the barium nitrate solution from yellow to a pink colour.

***Barium nitrate R***

$Ba(NO_3)_2$ (SRIP, 1963, p. 47).

***Barium oxide R***

BaO.

*Description.* White to yellowish-white lumps or powder. Absorbs moisture and carbon dioxide on exposure to air.

*Storage.* Store in tightly closed containers.

***Barium sulfate suspension TS***

*Procedure.* Mix 15 mL of barium chloride (0.5 mol/L) VS with 55 mL of water and 20 mL of sulfate-free ethanol (~750 g/L) TS, add 5 mL of potassium sulfate (174 mg/L) TS and dilute with sufficient water to produce 100 mL.

*Note.* Barium sulfate suspension TS must be freshly prepared.

***Beef extract R***

A residue from beef broth obtained by extracting fresh, sound, lean beef by cooking with water and evaporating the resulting broth at a low temperature, usually under reduced pressure, until a thick pasty residue is obtained.

***Benzalkonium chloride TS***

A mixture of alkylbenzyldimethylammonium chlorides. It contains in 1 litre not less than 470 g and not more than 530 g of alkylbenzyldimethylammonium chlorides, calculated as $C_{22}H_{40}ClN$.

*Description.* A clear, colourless to pale yellow, syrupy liquid; odour, aromatic.

*Miscibility.* Miscible with water and ethanol (~750 g/L) TS.

*Assay.* Dissolve 4 g, accurately weighed, in sufficient water to produce 100 mL. Transfer 25 mL to a separator, add 25 mL of chloroform R, 10 mL of sodium hydroxide (0.1 mol/L) VS, and 10 mL of freshly prepared potassium iodide (50 g/L) TS. Shake well, allow to separate and run off the chloroform layer. Shake the aqueous solution with 3 further quantities of chloroform R, each of 10 mL, and discard the chloroform solutions. Add 40 mL of hydrochloric acid (~420 g/L) TS, cool and titrate with potassium iodate (0.05 mol/L) VS until the solution becomes pale brown in colour. Add 2 mL of chloroform R and continue the titration until the chloroform becomes colourless. Titrate a mixture of 20 mL of water, 6 mL of potassium iodide (80 g/L) TS and 40 mL of hydrochloric acid (~420 g/L) TS with potassium iodate (0.05 mol/L) VS in a similar manner; the difference between the titrations represents the amount of potassium iodate (0.05 mol/L) VS required. Each mL of potassium iodate (0.05 mol/L) VS is equivalent to 35.40 mg of $C_{22}H_{40}ClN$. Determine the mass density using a pycnometer as described in *1.3 Determination of mass density*, relative density and weight per millilitre and calculate in g/L the proportion of $C_{22}H_{40}ClN$.

*Note:* A solution in water foams strongly when shaken.

***Benzalkonium chloride TS1***

*Procedure.* Dilute 2 mL of benzalkonium chloride TS with sufficient water to produce 100 mL.

***Benzene R***

$C_6H_6$ (SRIP, 1963, p. 48).

***Benzethonium chloride R***

Benzyldimethyl[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]ammonium chloride. $C_{27}H_{42}ClNO_2$. CAS Reg. No. 121-54-0.

*Description* . White or yellowish-white powder.

*Solubility* . Very soluble in water and in ethanol (~750 g/L) TS, freely soluble in dichrloromethan R.

*Melting point.* About 158- 165 °C, after drying at 100- 105 to constant mass

*Storage*. Store protected from light.

***Benzethonium chloride (0.004 mol/L) VS***

*Procedure*. Dissolve 1.792 g of benzethonium chloride R, previously dried to constant mass at 100 °C to 105 °C, in water R and dilute to 1000.0 mL with the same solvent.

*Method of standardization.* Dissolve 0.350 g of the dried substance in 35 mL of a mixture of 30 volumes of anhydrous acetic acid R and 70 volumes of acetic anhydride R. Titrate with perchloric acid (0.1 mol/L) VS, using 0.05 mL of crystal violet /acetic acid TS1 as indicator. Carry out a blank titration. Each mL of perchloric acid (0.1 mol/L) VS is equivalent to 44.81 mg of $C_{27}H_{42}ClNO_2$.

***Benzoic acid R***

$C_7H_6O_2$. Contains not less than 99.8% of $C_7H_6O_2$.

*Description.* Colourless, light, feathery crystals or a white, microcrystalline powder; odour, characteristic, faint.

*Solubility.* Slightly soluble in water; freely soluble in ethanol (~750 g/L) TS and ether R.

*Methanol-insoluble substances.* Dissolve 20 g in 200 mL of methanol R and digest under complete reflux for 30 minutes. Filter through a tared filtering crucible, wash thoroughly with methanol R and dry at 105 °C; it leaves a residue of not more than 1.0 mg.

*Assay.* Dissolve about 0.5 g, accurately weighed, in 15 mL of ethanol (~750 g/L) TS, previously neutralized to phenol red/ethanol TS, add 20 mL of water and titrate with sodium hydroxide (0.1 mol/L) VS, using phenol red/ethanol TS as indicator. Repeat the operation without the substance being examined and make any necessary correction. Each mL of sodium hydroxide (0.1 mol/L) VS is equivalent to 12.21 mg of $C_7H_6O_2$.

***Benzophenone R***

Diphenyl ketone; $C_{13}H_{10}O$.

A commercially available reagent of suitable grade.

*Melting point.* About 49 °C.

***Benzoyl chloride R***

$C_7H_5ClO$ (SRIP, 1963, p. 50).

***Benzoyl peroxide, hydrous R***

$C_{14}H_{10}O_4,\times H_2O$.

A commercially available reagent of suitable grade.

*Description.* A white, amorphous or granular powder.

*Note* : For safety reasons it should be kept moistened with about 23% w/w water.

***Benzyl alcohol R***

$C_7H_8O$.

*Description.* A colourless liquid; almost odourless.

*Miscibility.* Miscible with 25 parts of water; miscible with ethanol (~750 g/L) TS and ether R.

*Boiling temperature.* About 204 °C.

*Mass density.* $\rho_{20}$ = about 1.05 kg/L.

***Benzyl benzoate R***

$C_{14}H_{12}O_2$.

Benzyl benzoate as described in the monograph for *Benzyl benzoate*.

A commercially available reagent of suitable grade.

*Description.* A clear, colourless, oily liquid.

***Benzylpenicillin sodium R***

$C_{16}H_{17}N_2NaO_4S$. Contains not less than 96.0% and not more than 102.0% of $C_{16}H_{17}N_2NaO_4S$, calculated with reference to the dried substance.

*Description.* A white or almost white, crystalline powder; odourless or with a faint characteristic odour.

*Solubility.* Soluble in about 0.5 part of water; practically insoluble in ether R.

***Benzylpenicillin sodium TS***

*Procedure.* Dissolve 0.03 g of benzylpenicillin sodium R in sufficient phosphate buffer, pH 7.0, TS, to produce 10 mL. This solution contains not less than 3 mg/mL of benzylpenicillin sodium R.

***4,4'-Bis(dimethylamino)benzophenone R***

Tetramethyldiaminobenzophenone; $C_{17}H_{20}N_2O$.

*Other name.* Michler's ketone.

*Melting point.* About 176 °C.

***Bismuth oxynitrate R***

Approximately $4BiNO_3(OH)_2,BiO(OH)$ (SRIP, 1963, p. 50).

***Bismuth subnitrate R***

Bismuth hydroxide nitrate oxide; $Bi_5O(OH)_9(NO_3)_4$. Bismuth subnitrate is a basic salt, the composition of which varies with the conditions under which it is prepared. It contains not less than 71.5% and not more than 74.5% of Bi, calculated with reference to the dried substance.

*Description.* A white powder.

*Solubility.* Practically insoluble in water and ethanol (~750 g/L) TS; soluble in hydrochloric acid (~250 g/L) TS and nitric acid (~1000 g/L) TS.

***Blue tetrazolium R***

$C_{40}H_{32}Cl_2N_8O_2$. 3,3'-Dianisole-bis-[4,4'-(3,5-diphenyl) tetrazolium chloride].

*Description.* Lemon-yellow crystals.

*Solubility.* Slightly soluble in water; freely soluble in ethanol (~750 g/L) TS and methanol R; practically insoluble in acetone R and ether R.

*Molar absorptivity.* Its molar absorptivity in methanol R at 252 nm, is not less than 60 000.

*Suitability test.* Prepare the following standard solution: Dissolve in ethanol (~750 g/L) TS a suitable quantity of hydrocortisone R, previously dried at 105 °C for 3 hours and accurately weighed, and prepare by a step-by-step dilution a solution containing about 30 µg/mL. Transfer 10, 15 and 20 mL quantities of the standard solution to separate glass-stoppered 50ml conical flasks. Add 10 mL and 5 mL, respectively, of ethanol (~750 g/L) TS to the flasks containing the 10 and 15 mL quantities of the standard solution and swirl to mix. To each of the flasks, and to a fourth flask, representing the blank, containing 20 mL of ethanol (~750 g/L) TS, add 2.0 mL of a solution prepared by dissolving 0.05 g of the blue tetrazolium R in 10 mL of ethanol (~750 g/L) TS, mix and then add 2.0 mL of tetramethylammonium hydroxide/ethanol TS. Mix, allow the flasks to stand in the dark for 90 minutes and determine the absorbances at 525 nm against the blank. Plot the absorbances on the abscissa and the amount of hydrocortisone on the ordinate scale of arithmetic coordinate paper and draw the curve of best fit; the absorbance of each solution is proportional to the concentration and the absorbance of the solution containing 200 µg of hydrocortisone is not less than 0.50.

***Blue tetrazolium/ethanol TS***

*Procedure.* Dissolve 0.5 g of blue tetrazolium R in sufficient aldehyde-free ethanol (~750 g/L) TS, warming slightly if necessary, to produce 100 mL.

***Blue tetrazolium/sodium hydroxide TS***

*Procedure.* Immediately before use mix 1 volume of a 2 mg/mL solution of blue tetrazolium R in water with 3 volumes of a 0.12 g/mL solution of sodium hydroxide R in methanol TS.

***Borate buffer, pH 8.0, TS***

*Procedure.* Dissolve 0.25 g of boric acid R and 0.30 g of potassium chloride R in 50 mL of carbon-dioxide-free water R, add 3.97 mL of carbonate-free sodium hydroxide (0.2 mol/L) VS, and dilute with sufficient carbon-dioxide-free water R to produce 200 mL.

***Borate buffer, pH 9.0, TS***

*Procedure.* Dissolve 1.24 g of boric acid R in about 100 mL of water, add 8.3 mL of sodium hydroxide (1 mol/L) VS and add sufficient water to produce 200 mL.

***Borate buffer, pH 9.6, TS***

*Procedure.* Dissolve 0.25 g of boric acid R and 0.30 g of potassium chloride R in 50 mL of carbon-dioxide-free water R, add 36.85 mL of carbonate-free sodium hydroxide (0.2 mol/L) VS and dilute with sufficient carbon-dioxide-free water R to produce 200 mL.

***Boric acid (50 g/L) TS***

A solution of boric acid R containing about 50 g/L of $H_3BO_3$.

***Boric acid R***

$H_3BO_3$. Contains not less than 99.0% of $H_3BO_3$.

*Description.* White crystals or scales of a somewhat pearly lustre or a white, crystalline powder.

*Solubility.* Soluble in 20 parts of water, in 3 parts of boiling water and in 16 parts of ethanol (~750 g/L) TS.

*Water-insoluble substances.* 1.0 g dissolves in 30 parts of water; the solution is clear and colourless.

*Ethanol-insoluble substances.* 1.0 g dissolves in 10 mL of boiling ethanol (~750 g/L) TS; the solution is not more than faintly turbid.

*Assay.* Dissolve about 1 g, accurately weighed, in 30 mL of water; add 50 mL of glycerol R, previously neutralized to phenolphthalein/ethanol TS and titrate with carbonate-free sodium hydroxide (1 mol/L) VS, using phenolphthalein/ethanol TS as indicator. Each mL of carbonate-free sodium hydroxide (1 mol/L) VS is equivalent to 61.83 mg of $H_3BO_3$.

***Brilliant green R***

[4-[*p*-(Diethylamino)-α-phenylbenzylidene]-2,5-cyclohexadien-1-ylidene]diethylammonium hydrogen sulfate; $C_{27}H_{34}N_2O_4S$; C.I. 42040; Malachite green G; C.I. Basic green 1.

*Description.* Small, glistening, golden crystals.

***Brilliant green/acetic acid TS***

*Procedure.* Dissolve 0.5 g of brilliant green R in sufficient glacial acetic acid R1 to produce 100 mL.

***Bromine AsTS***

*Procedure.* Dissolve 30 g of potassium bromide R in 40 mL of water, add 30 g of bromine R and dilute with sufficient water to produce 100 mL. The solution complies with the following test: evaporate 10 mL nearly to dryness on a water-bath, add 50 mL of water, 10 mL of hydrochloric acid (~250 g/L) AsTS, sufficient stannous chloride AsTS to reduce the remaining bromine and apply the general test for arsenic. The colour of the stain produced is not more intense than that produced from a 1 mL standard stain, showing that the amount of arsenic does not exceed 1 µg/mL.

***Bromine R***

$Br_2$ (SRIP, 1963, p. 51).

***Bromine TS1***

A saturated solution of bromine R.

***Bromocresol green R***

$C_{21}H_{14}Br_4O_5S$ (SRIP, 1963, p. 52).

***Bromocresol green TS1***

*Procedure.* Dissolve 0.05 g of bromocresol green R and 1.021 g of potassium hydrogen phthalate R in 6 mL of sodium hydroxide (0.2 mol/L) VS and dilute to 100 mL with water. Filter if necessary.

***Bromocresol green/ethanol TS***

*Procedure.* Warm 0.1 g of bromocresol green R with 2.9 mL of sodium hydroxide (0.05 mol/L) VS and 5 mL of ethanol (~710 g/L) TS; after solution has been effected add a sufficient quantity of ethanol (~150 g/L) TS to produce 250 mL.

***Bromocresol purple R***

$C_{21}H_{16}Br_2O_5S$ (SRIP, 1963, p. 52).

***Bromocresol purple/ethanol TS.***

*Procedure.* Dissolve 0.05 g of bromocresol purple R in 100 mL of ethanol (~750 g/L) TS and filter if necessary.

***Bromophenol blue (1g/L) TS.***

A solution of bromophenol blue R containing about 1.0 g of $C_{19}H_{10}Br_4O_5S$ per litre.

***Bromophenol blue R***

$C_{19}H_{10}Br_4O_5S$ (SRIP, 1963, p. 52).

***Bromophenol blue TS***

*Procedure.* Dissolve 0.05 g of bromophenol blue R with gentle heating in 3.73 mL of sodium hydroxide (0.02 mol/L) VS and dilute to 100 mL with water.

***Bromophenol blue/ethanol TS.***

*Procedure.* Warm 0.1 g of bromophenol blue R with 3.2 mL of sodium hydroxide (0.05 mol/L) VS and 5 mL of ethanol (~710 g/L) TS; after solution has been effected add a sufficient quantity of ethanol (~150 g/L) TS to produce 250 mL.

***Bromothymol blue R***

$C_{27}H_{28}Br_2O_5S$ (SRIP, 1963, p. 53).

***Bromothymol blue/dimethylformamide TS***

*Procedure.* Dissolve 1.0 g of bromothymol blue R in sufficient dimethylformamide R to produce 100 mL.

***Bromothymol blue/ethanol TS***

*Procedure.* Warm 0.1 g of bromothymol blue R with 3.2 mL of sodium hydroxide (0.05 mol/L) VS and 5 mL of ethanol (~710 g/L) TS; after solution has been effected add a sufficient quantity of ethanol (~150 g/L) TS to produce 250 mL.

***Bromothymol blue/ethanol TS 2***

*Procedure*. Dissolve 50 mg of bromothymol blue R in a mixture of 4 mL of sodium hydroxide (~0.8 g/L) TS and 20 mL of ethanol (~750 g/L) R and dilute to 100 mL with water R.

Test for sensitivity. To 0.3 mL of bromothymol blue/ethanol TS2, add 100 mL of carbon dioxide-free water R. The solution is yellow. Not more than 0.1 mL of sodium hydroxide (~0.8 g/L) TSis required to change the colour to blue.

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

***Brown stock standard TS***

*Procedure.* To 35.0 mL of cobalt colour TS add 17.0 mL of copper colour TS, 8.0 mL of dichromate colour TS, dilute to 100.0 mL with iron colour TS and mix.

***1,3-Butanediol R***

$C_4H_{10}O_2$; CAS Reg. No. 107-88-0.

Contains not less than 99.0% of $C_4H_{10}O_2$.

***2-Butanol R***

$C_4H_{10}O$ (SRIP, 1963, p. 53).

***1-Butanol R***

[*n*-Butanol R]. $C_4H_{10}O$ (SRIP, 1963, p. 54).

***tert* -Butanol R**

2-Methylpropan-2-ol; $(CH_3)_3COH$.

*Description.* A colourless liquid or solid.

*Miscibility*. Miscible with water, ethanol (~750 g/L) TS and ether R.

*Boiling range.* Not less than 95% distils between 81 and 83 °C.

*Melting range.* 24–26 °C.

*Mass density.* $\rho_{20}$= 0.778–0.782 kg/L.

*Residue on evaporation.* Evaporate on a water-bath and dry to constant weight at 105 °C; it leaves a residue of not more than 0.05 mg/mL.

***Butyl acetate R***

$C_6H_{12}O_2$.

*Description.* A clear, colourless, flammable liquid; odour, characteristic.

*Miscibility*. Slightly miscible with water; miscible with ethanol (~750 g/L) TS.

*Mass density.* $\rho_{20}$ = about 0.88 kg/L.

***3-tert-Butyl-4-hydroxyanisole R***

$C_{11}H_{16}O_2$; 180.24; *[25013-16-5]*

*Description*. White to light yellow powder.

Use a suitable grade.

***tert-Butyl methyl ether R***

1,1-Dimethylethyl methyl ether; $C_5H_{12}O$.

A commercially available reagent of suitable grade.

*Description.* A clear, colourless liquid; inflammable.

*Refractive index.* $n_D^{20}$ = 1.3756.

*Relative density.* $d_4^{20}$ = 0.740–0.742.

***1-Butylamine R***

1-Aminobutane; $C_4H_{11}N$.

*Description.* A colourless to pale yellow inflammable liquid.

*Miscibility.* Miscible with water, ethanol (~750 g/L) TS and ether R.

*Boiling range.* Not less than 95% distils between 76 and 78 °C.

*Mass density,* $\rho_{20}$ = about 0.740 kg/L.

*Water.* Determine as described under *2.8 Determination of water by the Karl Fischer method* using about 5 mL of the liquid; not more than 10 mg/mL.

*Acid impurities.* To 50 mL add 5 drops of azo violet TS and titrate quickly with sodium methoxide (0.1 mol/L) VS to a deep blue end-point taking precautions to prevent absorption of atmospheric carbon dioxide, e.g. by use of an atmosphere of nitrogen; not more than 1.0 mL of sodium methoxide (0.1 mol/L) VS is required for neutralization.

***n-Butylamine***

$C_4H_{11}N$; Relative molecular mass 73.1; CAS Reg. No. 109-73-9; Butan-1-amine.

Distil and use within one month.

*Description.* Colourless liquid, miscible with water, with ethanol (96 per cent).

*Relative density.* About 1.401.

*Boiling point.* About 78 °C.

***Butylated hydroxyanisole R***

Use $C_{11}H_{16}O_2$.

Butylated hydroxyanisole as described in the monograph in *Butylated hydroxyanisole*.

***Butylated hydroxytoluene R.***

2,6-Di-*tert*-butyl-4-methylphenol, $C_{15}H_{24}O$.

*Description.* Colourless crystals, or a white, crystalline powder.

*Solubility.* Practically insoluble in water; freely soluble in ethanol (~750 g/L) TS; very soluble in ether R.

*Melting temperature.* About 70 °C.

*Sulfated ash.* Not more than 1.0 mg/g.