E - Endotoxin RS.... 1-Ethylquinaldinium iodide (15 g/L) TS

Endotoxin RS

Second WHO International Standard for Endotoxin as established in 1996, containing 10 000 IU per ampoule, approximately 1 µg of freeze-dried endotoxin from *Escherichia coli*, with 1 mg of PEG and 10 mg of lactose (distributed by the National Institute for Biological Standards and Control (NIBSC), PO Box 1193, Blanche Lane, South Mimms, Potters Bar, Herts EN6 3QH, England) or another suitable preparation, the activity of which has been determined in relation to the WHO International Standard using the gelation test.

Eosin Y (5 g/L) TS

A solution of eosin Y R containing about 5 g of $C_{20}H_6Br_4Na_2O_5$ per litre.

Eosin YR

Sodium tetrabromofluorescein; $C_{20}H_6Br_4N_2O_5$.

Description. Red to brownish lumps or a powder.

Solubility. Freely soluble in water; sparingly soluble in ethanol (~750 g/L) TS.

Epinephrine hydrogen tartrate R

Epinephrine hydrogen tartrate R as described in the monograph for *Epinephrine hydrogen tartrate*, which complies with the following test for the absence of levarterenol:

Levarterenol. Carry out descending *1.14.2 Paper chromatography*. Mix 4 volumes of 1-butanol R, 1 volume of glacial acetic acid R and 5 volumes of water, shake and allow the two layers to separate. Use the lower layer as the stationary phase and the upper layer as the mobile phase. Apply to the paper 20 µL of a solution containing 50 mg/mL of epinephrine hydrogen tartrate R, develop for 5 hours, dry the paper and spray with a freshly prepared 4.4 mg/mL solution of potassium ferricyanide R dissolved in buffer borate, pH 8.0, TS or another buffer having the same pH may be used; only 1 spot appears, which is pink.

Ergosterol R

Provitamin D_2; ergosta-5,7,22-trien-3-ol; $C_{28}H_{44}O$. Contains not less than 95.0% of $C_{28}H_{44}O$.

Description. White or almost white needles or a crystalline powder.

Melting temperature. About 163 °C.

Specific optical rotation. Use a 20 mg/mL solution in chloroform R; $[\alpha]_D^{20\,°C}$ = -133°.

Estradiol hemihydrate R

Estradiol hemihydrate of a suitable quality should be used.

Ethanol (~150 g/L) TS

A solution of about 200 mL of ethanol (~750 g/L) TS diluted with water to 1000 mL.

Ethanol (~375 g/L) TS

A solution of about 500 mL of ethanol (~750 g/L) TS diluted with water to 1000 mL.

Ethanol (~457 g/L) TS

Procedure. Dilute 609 mL of ethanol (~750 g/L) TS with sufficient water to produce 1000 mL.

Ethanol (~535 g/L) TS

Procedure. Dilute 713 mL of ethanol (~750 g/L) TS with sufficient water to produce 1000 mL.

Ethanol (~600 g/L) TS

A solution of about 800 mL of ethanol (~750 g/L) TS diluted with water to 1000 mL.

Ethanol (~675 g/L) TS

A solution of about 900 mL of ethanol (~750 g/L) TS diluted with water to 1000 mL.

Ethanol (~710 g/L) TS.

A solution of about 947 mL of ethanol (~750 g/L) TS diluted with water to 1000 mL.

Ethanol (~750 g/L) TS

[ethanol (95%) R] (SRIP, 1963, p. 84).

Ethanol (~750 g/L), aldehyde-free TS

[ethanol, aldehyde-free, (95%R]. (SRIP, 1963, p. 84).

Ethanol (~750 g/L), sulfate-free, TS

Ethanol (~750 g/L) TS that complies with the following test: evaporate 25 mL of ethanol (~750 g/L) TS to a volume of about 2 mL, add a mixture of 3 mL of hydrochloric acid (~70 g/L) TS and 42 mL of water and 5 mL of barium sulfate suspension TS. Proceed as described in *2.2.2 Limit test for sulfates*. Sulfate-free ethanol (~750 g/L) TS contains not more than 20 µg/mL.

Ethanol (80% v/v) TS

Procedure. Dilute 831 mL of ethanol (~750 g/L) TS to 1000 mL with water R.

Ethanol, dehydrated, R

C_2H_5OH (SRIP, 1963, p. 85).

Ethanol/methanol (95/5) TS

Procedure. To 5 mL of methanol R add 95 mL of dehydrated ethanol R.

Ethanol, neutralized, TS

Procedure. To a suitable quantity of ethanol (~750 g/L) TS add 0.5 mL of phenolphthalein/ethanol TS and just sufficient carbonate-free sodium hydroxide (0.02 mol/L) VS or (0.1 mol/L) VS to produce a faint pink colour.

Note: Prepare neutralized ethanol TS just prior to use.

Ether R

$C_4H_{10}O$ (SRIP, 1963, p. 85).

Ether, peroxide-free, R

Procedure. To 1000 mL of ether R add 20 mL of a solution of 30 g of ferrous sulfate R in 55 mL of water and shake the mixture with 3 mL of sulfuric acid (~1760 g/L) TS. Continue shaking until a small sample no longer produces a blue colour when shaken with an equal volume of a 20 g/L solution of potassium iodide R and 0.1 mL of starch TS.

Ethinylestradiol R

Ethinylestradiol of a suitable quality should be used.

Ethionamide R

Ethionamide of a suitable quality should be used.

Ethyl acetate R

$C_4H_8O_2$ (SRIP, 1963, p. 86).

Ethyl iodide R

C_2H_5I (SRIP, 1963, p. 87).

Ethylene glycol monoethyl ether R

$C_4H_{10}O_2$.

Description. A clear, colourless liquid.

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

Boiling range. Not less than 95% distils at between 133 and 135 °C.

Mass density (ρ_{20}). About 0.93 kg/L.

Ethylene glycol monomethyl ether R

2-Methoxyethanol; $C_3H_8O_2$.

Description. A colourless liquid.

Boiling temperature. About 125 °C.

Mass density. ρ_{20} = about 0.96 kg/L.

Ethylene glycol R

Ethane-1,2-diol; $C_2H_6O_2$; CAS Reg. No. 107-21-1.

Contains not less than 99.0% of $C_2H_6O_2$.

*Description.*Colourless, slightly viscous liquid, hygroscopic, miscible with water R and dehydrated ethanol R.

Relative density. d_{20}^{20} = 1.113 to 1.115.

Refraction index. n_D^{20} about 1.432.

Boiling point. About 198 °C.

Melting point. About -12 °C.

Acidity. To 10 mL, add 20 mL of water R and 1 mL of phenolphthalein/ethanol TS. Not more than 0.15 mL of sodium hydroxide (0.02 mol/L) VS is required to change the colour of the indicator to pink.

Water (*2.8*): Not more than 2 mg/g.

Ethylene oxide R

C_2H_4O.

A commercially available gas of suitable grade.

Ethylene oxide TS

Procedure. Weigh 1.0 g of cold ethylene oxide stock solution R (equivalent to 2.5 mg of ethylene oxide) into a cold flask containing 40 g of cold macrogol 200 TS. Mix and determine the exact mass and dilute to a calculated mass to obtain a solution containing 50 µg of ethylene oxide per 1.0 g of solution. Weigh 10.0 g into a flask and dilute with sufficient water to produce 50 mL (10 µg/mL of ethylene oxide). Dilute 10 mL of this solution to 50 mL with water (2 µg/mL of ethylene oxide).

Note : Ethylene oxide TS should be prepared immediately before use.

Ethylene oxide stock solution R

Note : *All operations should be carried out in a fume-hood. The operator must protect both hands and face by wearing polyethylene protective gloves and an appropriate face mask.*

Procedure. 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 TS. Determine the absorbed quantity of ethylene oxide by weighing before and after absorption. Dilute to 100 mL with macrogol 200 TS. Mix well before use.

Assay. To 10 mL of a 500 g/L suspension of magnesium chloride R in dehydrated ethanol R add 20 mL of hydrochloric acid/ethanol (0.1 mol/L) VS, stopper the flask, shake to obtain a saturated solution and allow to stand overnight to equilibrate. Weigh 5 g of the prepared ethylene oxide stock solution R (containing about 2.5 g/L) into the flask and allow to stand for 30 minutes. Titrate with potassium hydroxide/ethanol (0.1 mol/L) VS, determining the end-point potentiometrically. Carry out a blank titration, replacing the substance to be examined with the same quantity of macrogol 200 TS. Calculate the content of ethylene oxide in mg/g.

Storage. Keep in a tightly closed container in a refrigerator at 4 °C.

Ethylenediamine R

$C_2H_8N_2$.

Description. A colourless to pale yellow, clear liquid; odour, ammonia-like.

Miscibility. Miscible with water and ethanol (~750 g/L) TS; slightly miscible with ether R.

Boiling temperature. About 116 °C.

Mass density. ρ_{20} = about 0.898 kg/L.

Storage. Store in a tightly closed container, protected from air and acidic vapours.

2-Ethylhexanoic acid R

$C_8H_{16}O_2$

Molecular weight. 144.2.

*Description.*Colourless liquid.

Relative density d_{20}^{20}. About 0.91.

Related substances. Carry out the test as described under *1.14.1 Chromatography*, Gas chromatography using the conditions given in the test for 2-ethylhexanoic acid in the monograph on Potassium clavulanate. Prepare the following solution: suspend 0.2 g of 2-ethylhexanoic acid in 5 mL of water R, add 3 mL of 33% (V/V) solution of hydrochloric acid R and 5 mL of hexane R, shake for 1 minute, allow the layers to separate and use the upper layer. Inject 1 µL of this solution. The sum of the area of any peaks, other than the principal peak and the peak due to the solvent, is not greater than 2.5% of the area of the principal peak

Ethylmethylketone R

C_4H_8O.

Description. A clear, colourless, mobile liquid; odour, characteristic.

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

Boiling range. 79–80 °C.

Mass density. ρ_{20} = about 0.805 kg/L.

1-Ethylquinaldinium iodide R

1-Ethyl-2-methylquinolinium iodide; $C_{12}H_{14}IN$.

A commercially available reagent of suitable grade.

Description. A yellow-green solid.

Solubility. Sparingly soluble in water.

1-Ethylquinaldinium iodide (15 g/L) TS

A solution containing about 15 g of 1-ethylquinaldinium iodide R per litre.