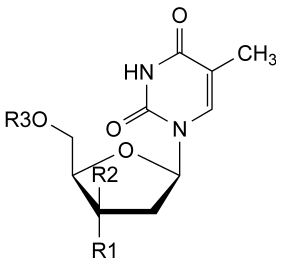
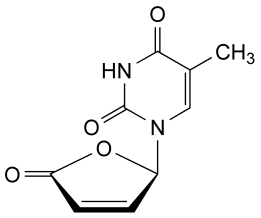


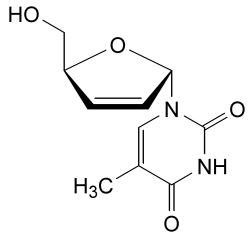
B. R1 = R3 = H, R2 = OH: 1-(2-deoxy-β-D-*threo*-pentofuranosyl)-5-methylpyrimidine-2,4(1*H*,3*H*)-dione (3′-epithymidine),

C. R1 = OH, R2 = R3 = H: 1-(2-deoxy-β-D-*erythro*-pentofuranosyl)-5-methylpyrimidine-2,4(1*H*,3*H*)-dione (thymidine),

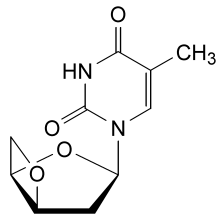
H. R1 = H, R2 = OH, R3 = $CH(CH_3)_2$: 1-[2-deoxy-5-*O*-(1-methylethyl)-β-D-*erythro*-pentofuranosyl]-5-methylpyrimidine-2,4(1*H*,3*H*)-dione,



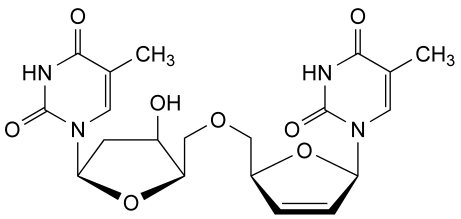
D. 1-[(2*R*)-5-oxo-2,5-dihydrofuran-2-yl]-5-methylpyrimidine-2,4(1*H*,3*H*)-dione,



E. 1-(2,3-dideoxy-α-D-*glycero*-pent-2-enofuranosyl)-5-methylpyrimidine-2,4(1*H*,3*H*)-dione (stavudine anomer α),



F. 1-(3,5-anhydro-2-deoxy-β-D-*threo*-pentofuranosyl)-5-methylpyrimidine-2,4(1*H*,3*H*)-dione,



G. 5′-*O*-[[(2*S*,5*R*)-5-(5-methyl-2,4-dioxo-3,4-dihydropyrimidine-1(2*H*)-yl)-2,5-dihydrofuran-2-yl]methyl]-3′-epithymidine.

01/2008:1474
corrected 6.0

STEARIC ACID

Acidum stearicum

DEFINITION

Mixture consisting mainly of stearic (octadecanoic) acid ($C_{18}H_{36}O_2$; M_r 284.5) and palmitic (hexadecanoic) acid ($C_{16}H_{32}O_2$; M_r 256.4) obtained from fats or oils of vegetable or animal origin.

Content:

Stearic acid 50	*Stearic acid*: 40.0 per cent to 60.0 per cent. *Sum of the contents of stearic and palmitic acids*: minimum 90.0 per cent.
Stearic acid 70	*Stearic acid*: 60.0 per cent to 80.0 per cent. *Sum of the contents of stearic and palmitic acids*: minimum 90.0 per cent.
Stearic acid 95	*Stearic acid*: minimum 90.0 per cent. *Sum of the contents of stearic and palmitic acids*: minimum 96.0 per cent.

CHARACTERS

Appearance: white or almost white, waxy, flaky crystals, white or almost white hard masses, or white or yellowish-white powder.

Solubility: practically insoluble in water, soluble in ethanol (96 per cent) and in light petroleum (50-70 °C).

IDENTIFICATION

A. It complies with the test for freezing point (see Tests).

B. Acid value (*2.5.1*): 194 to 212, determined on 0.5 g.

C. Examine the chromatograms obtained in the assay.

Results: the retention times of the principal peaks in the chromatogram obtained with the test solution are approximately the same as those of the principal peaks in the chromatogram obtained with the reference solution.

TESTS

Appearance. Heat the substance to be examined to about 75 °C. The resulting liquid is not more intensely coloured than reference solution Y_7 or BY_7 (*2.2.2, Method I*).

Acidity. Melt 5.0 g, shake for 2 min with 10 ml of hot *carbon dioxide-free water R*, cool slowly and filter. To the filtrate add 0.05 ml of *methyl orange solution R*. No red colour develops.

Iodine value (*2.5.4*). See Table 1474.-1.

Freezing point (*2.2.18*). See Table 1474.-1.

Table 1474.-1.

Type	Iodine value	Freezing point (°C)
Stearic acid 50	maximum 4.0	53 - 59
Stearic acid 70	maximum 4.0	57 - 64
Stearic acid 95	maximum 1.5	64 - 69

Nickel (*2.4.27*): maximum 1 ppm.

ASSAY

Gas chromatography (*2.2.28*): use the normalisation procedure.

Test solution. In a conical flask fitted with a reflux condenser, dissolve 0.100 g of the substance to be examined in 5 ml of *boron trifluoride-methanol solution R*. Boil under reflux for 10 min. Add 4.0 ml of *heptane R* through the condenser and boil again under reflux for 10 min. Allow to cool. Add 20 ml of a saturated solution of *sodium chloride R*. Shake and allow the layers to separate. Remove about 2 ml of the organic layer and dry it over 0.2 g of *anhydrous sodium sulphate R*. Dilute 1.0 ml of this solution to 10.0 ml with *heptane R*.

Reference solution. Prepare the reference solution in the same manner as the test solution using 50 mg of *palmitic acid CRS* and 50 mg of *stearic acid CRS* instead of the substance to be examined.

Column:
- *material*: fused silica;
- *size*: *l* = 30 m, Ø = 0.32 mm;
- *stationary phase*: *macrogol 20 000 R* (film thickness 0.5 µm).

Carrier gas: *helium for chromatography R*.

Flow rate: 2.4 ml/min.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 2	70
	2 - 36	70 → 240
	36 - 41	240
Injection port		220
Detector		260

Detection: flame ionisation.

Injection: 1 µl.

Relative retention with reference to methyl stearate: methyl palmitate = about 0.88.

System suitability: reference solution:
- *resolution*: minimum 5.0 between the peaks due to methyl stearate and methyl palmitate.

LABELLING

The label states the type of stearic acid (50, 70, 95).

01/2008:1268
corrected 6.0

STEAROYL MACROGOLGLYCERIDES

Macrogolglyceridorum stearates

DEFINITION

Mixtures of monoesters, diesters and triesters of glycerol and monoesters and diesters of macrogols with a mean relative molecular mass between 300 and 4000.

They are obtained by partial alcoholysis of saturated oils containing mainly triglycerides of stearic (octadecanoic) acid, using macrogol, or by esterification of glycerol and macrogol with saturated fatty acids, or by mixture of glycerol esters and condensates of ethylene oxide with the fatty acids of these hydrogenated oils.

The hydroxyl value is within 15 units of the nominal value. The saponification value is within 10 units of the nominal value.

CHARACTERS

Appearance: pale yellow waxy solid.

Solubility: dispersible in warm water and in warm liquid paraffin, freely soluble in methylene chloride, soluble in warm anhydrous ethanol.

IDENTIFICATION

A. Thin-layer chromatography (*2.2.27*).

Test solution. Dissolve 1.0 g of the substance to be examined in *methylene chloride R* and dilute to 20 ml with the same solvent.

Plate: *TLC silica gel plate R*.

Mobile phase: *hexane R, ether R* (30:70 *V/V*).

Application: 10 µl.

Development: over a path of 15 cm.

Drying: in air.

Detection: spray with a 0.1 g/l solution of *rhodamine B R* in *ethanol (96 per cent) R* and examine in ultraviolet light at 365 nm.

Results: the chromatogram shows a spot due to triglycerides with an R_F value of about 0.9 (R_{st} 1) and spots due to 1,3-diglycerides (R_{st} 0.7), to 1,2-diglycerides (R_{st} 0.6), to monoglycerides (R_{st} 0.1) and to esters of macrogol (R_{st} 0).

B. Hydroxyl value (see Tests).

C. Saponification value (see Tests).

D. Fatty acid composition (see Tests).

TESTS

Acid value (*2.5.1*): maximum 2.0, determined on 2.0 g.

Hydroxyl value (*2.5.3, Method A*): within 15 units of the nominal value, determined on 1.0 g.

Peroxide value (*2.5.5, Method A*): maximum 6.0, determined on 2.0 g.

Saponification value (*2.5.6*): within 10 units of the nominal value, determined on 2.0 g.

Alkaline impurities. Into a test-tube introduce 5.0 g and carefully add a mixture, neutralised if necessary with *0.01 M hydrochloric acid* or with *0.01 M sodium hydroxide,* of 0.05 ml of a 0.4 g/l solution of *bromophenol blue R* in *ethanol (96 per cent) R*, 0.3 ml of *water R* and 10 ml of *ethanol (96 per cent) R*. Shake and allow to stand. Not more than 1.0 ml of *0.01 M hydrochloric acid* is required to change the colour of the upper layer to yellow.

Free glycerol: maximum 3.0 per cent.

Dissolve 1.20 g in 25.0 ml of *methylene chloride R*. Heat if necessary. After cooling, add 100 ml of *water R*. Shake and add 25.0 ml of *periodic acetic acid solution R*. Shake and allow to stand for 30 min. Add 40 ml of a 75 g/l solution of *potassium iodide R*. Allow to stand for 1 min. Add 1 ml of *starch solution R*. Titrate the iodine with *0.1 M sodium thiosulphate*. Carry out a blank titration.

1 ml of *0.1 M sodium thiosulphate* is equivalent to 2.3 mg of glycerol.

Composition of fatty acids. Gas chromatography (*2.4.22, Method A*).

Composition of the fatty-acid fraction of the substance:
- *lauric acid*: maximum 5.0 per cent;
- *myristic acid*: maximum 5.0 per cent;
- *stearic acid and palmitic acid*: different nominal amounts and minimum 90.0 per cent for the sum of $C_{18}H_{36}O_2$ and $C_{16}H_{32}O_2$.

Ethylene oxide and dioxan (*2.4.25*): maximum 1 ppm of ethylene oxide and maximum 10 ppm of dioxan.