– *palmitic acid*: 8.0 per cent to 12.0 per cent,
– *stearic acid*: 1.0 per cent to 5.0 per cent,
– *oleic acid*: 5.0 per cent to 10.0 per cent,
– *linoleic acid*: not more than 3.0 per cent.

Ethylene oxide and dioxan (*2.4.25*). Not more than 1 ppm of ethylene oxide and not more than 10 ppm of dioxan.

Water (*2.5.12*). Not more than 1.0 per cent, determined on 1.0 g by the semi-micro determination of water.

Total ash (*2.4.16*). Not more than 0.3 per cent, determined on 1.0 g.

LABELLING

The label states the number of ethylene oxide units per molecule (nominal value).

01/2005:1083

MACROGOLGLYCEROL HYDROXYSTEARATE

Macrogolglyceroli hydroxystearas

DEFINITION

Contains mainly trihydroxystearyl glycerol ethoxylated with 7 to 60 molecules of ethylene oxide (nominal value), with small amounts of macrogol hydroxystearate and of the corresponding free glycols. It results from the reaction of hydrogenated castor oil with ethylene oxide.

CHARACTERS

Appearance: if less than 10 units of ethylene oxide per molecule: yellowish, turbid, viscous liquid; if more than 20 units of ethylene oxide per molecule: white or yellowish semi-liquid or pasty mass.

Solubility: if less than 10 units of ethylene oxide per molecule: practically insoluble in water, soluble in acetone, dispersible in alcohol; if more than 20 units of ethylene oxide per molecule: freely soluble in water, in acetone and in alcohol, practically insoluble in light petroleum.

IDENTIFICATION

A. It complies with the test for iodine value (see Tests).
B. It complies with the test for saponification value (see Tests).
C. Thin-layer chromatography (*2.2.27*).

Test solution. To 1 g of the substance to be examined, add 100 ml of a 100 g/l solution of *potassium hydroxide R* and boil under a reflux condenser for 30 min. Allow to cool. Acidify the solution with 20 ml of *hydrochloric acid R*. Shake the mixture with 50 ml of *ether R* and allow to stand until separation of the layers is obtained. Transfer the clear upper layer to a suitable tube, add 5 g of *anhydrous sodium sulphate R*, close the tube and allow to stand for 30 min. Filter and evaporate the filtrate to dryness on a water-bath. Dissolve 50 mg of the residue in 25 ml of *ether R*.

Reference solution. Dissolve 50 mg of *12-hydroxystearic acid R* in *methylene chloride R* and dilute to 25 ml with the same solvent.

Plate: *TLC octadecylsilyl silica gel plate R*.

Mobile phase: *methylene chloride R, glacial acetic acid R, acetone R* (10:40:50 *V/V/V*).

Application: 2 µl.

Development: over a path of 8 cm.

Drying: in a current of cold air.

Detection: spray with a 80 g/l solution of *phosphomolybdic acid R* in *2-propanol R* and heat at 120 °C for about 1-2 min.

Results: the principal spot in the chromatogram obtained with the test solution is similar in position and colour to the principal spot in the chromatogram obtained with the reference solution.

D. Place about 2 g in a test-tube and add 0.2 ml of *sulphuric acid R*. Close the tube using a stopper fitted with a glass tube bent twice at right angles. Heat the tube until white fumes appear. Collect the fumes in 1 ml of *mercuric chloride solution R*. A white precipitate is formed and the fumes turn a filter paper impregnated with *alkaline potassium tetraiodomercurate solution R* black.

TESTS

Solution S. Dissolve 5.0 g of macrogolglycerol hydroxystearate with less than 10 units of ethylene oxide per molecule in a mixture of 50 volumes of *acetone R* and 50 volumes of *ethanol R* and dilute to 50 ml with the same mixture of solvents.

Dissolve 5.0 g of macrogolglycerol hydroxystearate with more than 20 units of ethylene oxide per molecule in *carbon dioxide-free water R* and dilute to 50 ml with the same solvent.

Appearance of solution. Solution S is not more opalescent than reference suspension III (*2.2.1*) and not more intensely coloured than reference solution BY_6 (*2.2.2, Method II*).

Alkalinity. To 2 ml of solution S add 0.5 ml of *bromothymol blue solution R1*. The solution is not blue.

Acid value (*2.5.1*): maximum 2.0, determined on 5.0 g.

Hydroxyl value (*2.5.3, Method A*). See Table 1083.-1.

Iodine value (*2.5.4*): maximum 5.0.

Saponification value (*2.5.6*). See Table 1083.-1.

Table 1083.-1

Ethylene oxide units per molecule (nominal value)	Hydroxyl value	Saponification value
7	115 - 135	125 - 140
25	70 - 90	70 - 90
40	60 - 80	45 - 69
60	45 - 67	40 - 51

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

Heavy metals (*2.4.8*).

Substances soluble in acetone/ethanol: maximum 10 ppm.

12 ml of solution S complies with limit test B. Prepare the standard using lead standard solution (1 ppm Pb) obtained by diluting *lead standard solution (100 ppm Pb) R* with a mixture of equal volumes of *acetone R* and *ethanol R*.

Substances soluble in water: maximum 10 ppm.

12 ml of solution S complies with limit test A. Prepare the standard using *lead standard solution (1 ppm Pb) R*.

Water (*2.5.12*): maximum 3.0 per cent, determined on 2.000 g.

Total ash (*2.4.16*): maximum 0.3 per cent, determined on 2.0 g.

LABELLING

The label states the number of ethylene oxide units per molecule (nominal value).