Composition of fatty acids (*2.4.22, Method C*). Use the mixture of calibrating substances in Table 2.4.22.-3.

Composition of the fatty-acid fraction of the substance:

– *myristic acid*: maximum 5.0 per cent;
– *palmitic acid*: maximum 16.0 per cent;
– *palmitoleic acid*: maximum 8.0 per cent;
– *stearic acid*: maximum 6.0 per cent;
– *oleic acid*: minimum 58.0 per cent;
– *linoleic acid*: maximum 18.0 per cent;
– *linolenic acid*: maximum 4.0 per cent.

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

Water (*2.5.12*): maximum 0.5 per cent, determined on 0.50 g.

Sulphated ash: maximum 0.25 per cent.

Heat a silica crucible to redness for 30 min, allow to cool in a desiccator and weigh. Evenly distribute 1.0 g of the substance to be examined in the crucible and weigh. Dry at 100-105 °C for 1 h and ignite in a muffle furnace at 600 ± 25 °C, until the substance is thoroughly charred. Carry out the test for sulphated ash (*2.4.14*) on the residue obtained, starting from “Moisten the substance to be examined...”.

STORAGE

In an airtight container, protected from light.

01/2008:1234

MACROGOL STEARATE

Macrogoli stearas

DEFINITION

Mixture of monoesters and diesters of mainly stearic (octadecanoic) acid and/or palmitic (hexadecanoic) acid and macrogols. It may be obtained by ethoxylation or by esterification of macrogols with stearic acid 50 (type I) or stearic acid 95 (type II) (see *Stearic acid (1474)*). It may contain free macrogols. The average polymer length is equivalent to 6 to 100 ethylene oxide units per molecule (nominal value).

CHARACTERS

Appearance: white or slightly yellowish waxy mass.

Solubility: soluble in alcohol and in 2-propanol. Macrogol stearate corresponding to a product with 6 to 9 units of ethylene oxide per molecule is practically insoluble, but freely dispersible in water and miscible with fatty oils and with waxes. Macrogol stearate corresponding to a product with 20 to 100 units of ethylene oxide per molecule is soluble in water and practically insoluble in fatty oils and in waxes.

IDENTIFICATION

A. It complies with the test for saponification value (see Tests).
B. It complies with the test for composition of fatty acids (see Tests).

TESTS

Alkalinity. Dissolve 2.0 g in *alcohol R* and dilute to 20 ml with the same solvent. To 2 ml of this solution add 0.05 ml of *phenol red solution R*. The solution is not red.

Melting point (*2.2.15*). See Table 1234.-1.

Melt about 10 g at 80-90 °C. Introduce into the tube by capillary action, a sufficient amount of the substance, to form in the tube a column of the prescribed height. Allow to stand at 0 °C for 2 h.

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

Hydroxyl value (*2.5.3, Method A*). See Table 1234.-1.

Iodine value (*2.5.4*): maximum 2.0.

Saponification value (*2.5.6*). See Table 1234.-1.

Table 1234.-1

Ethylene oxide units per molecule (nominal value)	Melting point (°C)	Hydroxyl value	Saponification value
6		90 - 110	85 - 105
8 - 9	26 - 35	80 - 105	88 - 100
20	33 - 40	50 - 62	46 - 56
40 - 50	38 - 52	23 - 40	20 - 35
100	48 - 60	15 - 30	5 - 20

Reducing substances. Dissolve or disperse 2.0 g in *water R* and dilute to 20 ml with the same solvent. Mix 1.0 ml of the solution with 9 ml of *0.1 M sodium hydroxide* and 0.5 ml of *triphenyltetrazolium chloride solution R*. Heat in a water-bath at 70 °C. After 5 min, the solution is not more intensely coloured than a mixture of 0.15 ml of yellow primary solution, 0.9 ml of red primary solution and 8.95 ml of a 10 g/l solution of *hydrochloric acid R* (*2.2.2, Method II*).

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

Composition of the fatty acid fraction of the substance:

	Type of fatty acid used	Composition of fatty acids
Macrogol stearate type I	Stearic acid 50	*Stearic acid*: 40.0 per cent to 60.0 per cent, *Sum of the contents of palmitic and stearic acids*: not less than 90.0 per cent.
Macrogol stearate type II	Stearic acid 95	*Stearic acid*: 90.0 per cent to 99.0 per cent, *Sum of the contents of palmitic and stearic acids*: not less than 96.0 per cent.

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

Heavy metals (*2.4.8*): maximum 10 ppm.

2.0 g complies with limit test C. Prepare the standard using 2 ml of *lead standard solution (10 ppm Pb) R*.

Water (*2.5.12*): maximum 3.0 per cent, determined on 0.50 g. Use as the solvent a mixture of equal volumes of *anhydrous methanol R* and *methylene chloride R*.

Total ash (*2.4.16*): maximum 0.3 per cent, determined on 1.0 g.

STORAGE

In an airtight container.

LABELLING

The label states:

– the number of ethylene oxide units per molecule (nominal value),
– the type of macrogol stearate.