Water (*2.5.12*): maximum 3.0 per cent, determined on 1.00 g.

Total ash (*2.4.16*): maximum 0.25 per cent, determined on 2.0 g.

STORAGE

In an airtight container, protected from light.

01/2008:1914

POLYSORBATE 40

Polysorbatum 40

DEFINITION

Mixture of partial esters of fatty acids, mainly *Palmitic acid (1904)*, with sorbitol and its anhydrides ethoxylated with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides.

CHARACTERS

Appearance: oily, viscous, yellowish or brownish-yellow liquid.

Solubility: miscible with water, with ethanol, with ethyl acetate and with methanol, practically insoluble in fatty oils and in liquid paraffin.

Relative density: about 1.10.

Viscosity: about 400 mPa·s at 30 °C.

IDENTIFICATION

First identication: A, D.

Second identification: B, C, D, E.

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison: *Ph. Eur. reference spectrum of polysorbate 40.*

B. It complies with the test for hydroxyl value (see Tests).

C. It complies with the test for saponification value (see Tests).

D. It complies with the test for composition of fatty acids (see Tests).

E. Dissolve 0.1 g in 5 ml of *methylene chloride R*. Add 0.1 g of *potassium thiocyanate R* and 0.1 g of *cobalt nitrate R*. Stir with a glass rod. The solution becomes blue.

TESTS

Acid value (*2.5.1*): maximum 2.0.

Dissolve 5.0 g in 50 ml of the prescribed mixture of solvents.

Hydroxyl value (*2.5.3, Method A*): 89 to 105.

Peroxide value: maximum 10.0.

Introduce 10.0 g into a 100 ml beaker, dissolve with *glacial acetic acid R* and dilute to 20 ml with the same solvent. Add 1 ml of *saturated potassium iodide solution R* and allow to stand for 1 min. Add 50 ml of *carbon dioxide-free water R* and a magnetic stirring bar. Titrate with *0.01 M sodium thiosulphate*, determining the end-point potentiometrically (*2.2.20*). Carry out a blank titration.

Determine the peroxide value using the following expression:

$$\frac{(n_1 - n_2) \times M \times 1000}{m}$$

n_1 = volume of *0.01 M sodium thiosulphate* required for the substance to be examined, in millilitres,

n_2 = volume of *0.01 M sodium thiosulphate* required for the blank, in millilitres,

M = molarity of the sodium thiosulphate solution, in moles per litre,

m = mass of substance to be examined, in grams.

Saponification value (*2.5.6*): 41 to 52, determined on 4.0 g.

Use 15.0 ml of *0.5 M alcoholic potassium hydroxide* and dilute with 50 ml of *alcohol R* before carrying out the titration. Heat under reflux for 60 min.

Composition of fatty acids (*2.4.22, Method C*). Prepare reference solution (a) as indicated in Table 2.4.22.-1.

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.*

Linear velocity: 50 cm/s.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 14	80 → 220
	14 - 54	220
Injection port		250
Detector		250

Detection: flame ionisation.

Injection: 1 µl.

Composition of the fatty acid fraction of the substance:

– *palmitic acid*: minimum 92.0 per cent.

Ethylene oxide and dioxan (*2.4.25, Method A*): maximum 1 ppm of ethylene oxide and maximum 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 1.00 g.

Total ash (*2.4.16*): maximum 0.25 per cent, determined on 2.0 g.

STORAGE

In an airtight container, protected from light.

01/2008:0427

POLYSORBATE 60

Polysorbatum 60

DEFINITION

Mixture of partial esters of fatty acids, mainly *Stearic acid 50 (1474)*, with sorbitol and its anhydrides ethoxylated with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides.

CHARACTERS

Appearance: yellowish-brown gelatinous mass which becomes a clear liquid at temperatures above 25 °C.

Solubility: soluble in water, in ethanol, in ethyl acetate and in methanol, practically insoluble in fatty oils and in liquid paraffin.

Relative density: about 1.10.

Viscosity: about 400 mPa·s at 30 °C.

IDENTIFICATION

First identication: A, D.

Second identification: B, C, D, E.

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison: *Ph. Eur. reference spectrum of polysorbate 60.*

B. It complies with the test for hydroxyl value (see Tests).

C. It complies with the test for saponification value (see Tests).

D. It complies with the test for composition of fatty acids (see Tests).

E. Dissolve 0.1 g in 5 ml of *methylene chloride R*. Add 0.1 g of *potassium thiocyanate R* and 0.1 g of *cobalt nitrate R*. Stir with a glass rod. The solution becomes blue.

TESTS

Acid value (*2.5.1*): maximum 2.0.

Dissolve 5.0 g in 50 ml of the prescribed mixture of solvents.

Hydroxyl value (*2.5.3, Method A*): 81 to 96.

Peroxide value: maximum 10.0.

Introduce 10.0 g into a 100 ml beaker, dissolve with *glacial acetic acid R* and dilute to 20 ml with the same solvent. Add 1 ml of *saturated potassium iodide solution R* and allow to stand for 1 min. Add 50 ml of *carbon dioxide-free water R* and a magnetic stirring bar. Titrate with *0.01 M sodium thiosulphate*, determining the end-point potentiometrically (*2.2.20*). Carry out a blank titration.

Determine the peroxide value using the following expression:

$$\frac{(n_1 - n_2) \times M \times 1000}{m}$$

n_1 = volume of *0.01 M sodium thiosulphate* required for the substance to be examined, in millilitres,

n_2 = volume of *0.01 M sodium thiosulphate* required for the blank, in millilitres,

M = molarity of the sodium thiosulphate solution, in moles per litre,

m = mass of substance to be examined, in grams.

Saponification value (*2.5.6*): 45 to 55, determined on 4.0 g.

Use 15.0 ml of *0.5 M alcoholic potassium hydroxide* and dilute with 50 ml of *alcohol R* before carrying out the titration. Heat under reflux for 60 min.

Composition of fatty acids (*2.4.22, Method C*). Prepare reference solution (a) as indicated in Table 2.4.22.-1.

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.*

Linear velocity: 50 cm/s.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 14	80 → 220
	14 - 54	220
Injection port		250
Detector		250

Detection: flame ionisation.

Injection: 1 µl.

Composition of the fatty acid fraction of the substance:

– *stearic acid*: 40.0 per cent to 60.0 per cent,

– *sum of the contents of palmitic and stearic acids*: minimum 90.0 per cent.

Ethylene oxide and dioxan (*2.4.25, Method A*): maximum 1 ppm of ethylene oxide and maximum 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 1.00 g.

Total ash (*2.4.16*): maximum 0.25 per cent, determined on 2.0 g.

STORAGE

In an airtight container, protected from light.

01/2008:0428

POLYSORBATE 80

Polysorbatum 80

DEFINITION

Mixture of partial esters of fatty acids, mainly *Oleic acid (0799)*, with sorbitol and its anhydrides ethoxylated with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides.

CHARACTERS

Appearance: oily, yellowish or brownish-yellow, clear or slightly opalescent liquid.

Solubility: dispersible in water, in anhydrous ethanol, in ethyl acetate and in methanol, practically insoluble in fatty oils and in liquid paraffin.

Relative density: about 1.10.

Viscosity: about 400 mPa·s at 25 °C.

IDENTIFICATION

First identication: A, D.

Second identification: B, C, D, E.

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison: *Ph. Eur. reference spectrum of polysorbate 80.*

B. Hydroxyl value (see Tests).

C. Saponification value (see Tests).

D. Composition of fatty acids (see Tests).

E. Dissolve 0.1 g in 5 ml of *methylene chloride R*. Add 0.1 g of *potassium thiocyanate R* and 0.1 g of *cobalt nitrate R*. Stir with a glass rod. The solution becomes blue.