



Edition: BP 2025 (Ph. Eur. 11.6 update)

Macrogol Cetostearyl Ether

[General Notices](#)

(Ph. Eur. monograph 1123)

Action and use

Non-ionic surfactant.

Ph Eur

DEFINITION

Mixture of ethers of mixed macrogols with linear fatty alcohols, mainly cetostearyl alcohol. It may contain some free macrogols and it contains various amounts of free cetostearyl alcohol. The number of moles of ethylene oxide reacted per mole of cetostearyl alcohol is 2 to 33 (nominal value).

CHARACTERS

Appearance

White or yellowish-white, waxy, unctuous mass, pellets, microbeads or flakes.

Solubility

— macrogol cetostearyl ether with low numbers of moles of ethylene oxide reacted per mole: practically insoluble in water, soluble in ethanol (96 per cent) and in methylene chloride;

— macrogol cetostearyl ether with higher numbers of moles of ethylene oxide reacted per mole: dispersible or soluble in water, soluble in ethanol (96 per cent) and in methylene chloride.

It solidifies at 32 °C to 52 °C.

IDENTIFICATION

- A. Hydroxyl value (see Tests).
- B. Iodine value (see Tests).
- C. Saponification value (see Tests).
- D. Thin-layer chromatography ([2.2.27](#)).

Test solution Dissolve the prescribed amount of substance to be examined (see table below) in a mixture of 1 volume of [water R](#) and 9 volumes of [methanol R](#) and dilute to 75 mL with the same mixture of solvents

Number of moles of ethylene oxide reacted per mole	Amount to be dissolved (g)
2 - 6	5.0
10 - 22	10.0
25 - 33	15.0

Add 60 mL of [hexane R](#) and shake for 3 min. The formation of foam can be reduced by the addition of some drops of [ethanol \(96 per cent\) R](#). Filter the upper layer through [anhydrous sodium sulfate R](#), wash the filter with 3 quantities, each of 10 mL, of [hexane R](#) and evaporate the combined filtrates to dryness. Dissolve 0.05 g of the residue in 10 mL of [methanol R](#) (the solution may be opalescent).

Reference solution Dissolve 25 mg of [stearyl alcohol CRS](#) in [methanol R](#) and dilute to 25 mL with the same solvent.

Plate [TLC silica gel plate R](#).

Mobile phase [ethyl acetate R](#).

Application 20 µL.

Development Over a path of 15 cm.

Drying In air.

Detection Spray with vanillin-sulfuric acid reagent prepared as follows: dissolve 0.5 g of [vanillin R](#) in 50 mL of [ethanol \(96 per cent\) R](#) and dilute to 100 mL with [sulfuric acid R](#); allow to dry in air; heat at about 130 °C for 15 min and allow to cool in air.

Results The chromatogram obtained with the test solution shows several spots; one of these spots corresponds to the principal spot in the chromatogram obtained with the reference solution.

E. Dissolve or disperse 0.1 g in 5 mL of [ethanol \(96 per cent\) R](#), add 2 mL of [water R](#), 10 mL of [dilute hydrochloric acid R](#), 10 mL of [barium chloride solution R1](#) and 10 mL of a 100 g/L solution of [phosphomolybdic acid R](#). A precipitate is formed.

TESTS

Appearance of solution

The solution is not more intensely coloured than reference solution BY₅ ([2.2.2, Method II](#)).

Dissolve 5.0 g in [ethanol \(96 per cent\) R](#) and dilute to 50 mL with the same solvent.

Alkalinity

Dissolve 2.0 g in a hot mixture of 10 mL of [ethanol \(96 per cent\) R](#) and 10 mL of [water R](#). Add 0.1 mL of [bromothymol blue solution R1](#). Not more than 0.5 mL of [0.1 M hydrochloric acid](#) is required to change the colour of the indicator to yellow.

[Acid value \(2.5.1\)](#)

Hydroxyl value (2.5.3, Method A)

Number of moles of ethylene oxide reacted per mole (nominal value)	Hydroxyl value
2	150 - 180
3	135 - 155
5 - 6	100 - 134
10	75 - 90
12	67 - 77
15	58 - 67
20 - 22	40 - 55
25	36 - 46
30 - 33	32 - 40

Iodine value (2.5.4, Method A)

Maximum 2.0.

Saponification value (2.5.6)

Maximum 3.0, determined on 10.0 g.

Ethylene oxide and dioxan (2.4.25)

Maximum 1 ppm of ethylene oxide and maximum 10 ppm of dioxan.

Water (2.5.12)

Maximum 3.0 per cent, determined on 2.00 g.

Total ash (2.4.16)

Maximum 0.2 per cent, determined on 2.0 g.

STORAGE

In an airtight container.

LABELLING

The label states the number of moles of ethylene oxide reacted per mole of cetostearyl alcohol (nominal value).

