British Pharmacopoeia | **Quality standards**

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Polyoxypropylene Stearyl Ether

[General Notices](#)

(Ph. Eur. monograph 2602)

Ph Eur

DEFINITION

Mixture of ethers of polyoxypropylene with linear alcohols, mainly stearyl alcohol, obtained by the reaction of stearyl alcohol with propylene oxide. It may contain some free polyoxypropylene and various amounts of free stearyl alcohol. The number of moles of propylene oxide reacted per mole of stearyl alcohol is 11 (nominal value). A suitable antioxidant may be added.

CHARACTERS

Appearance

Colourless or pale yellow, clear or slightly turbid liquid.

Solubility

Practically insoluble in water, soluble in ethanol (96 per cent), in mineral oils and in 2-propanol, practically insoluble in propylene glycol and in glycerol.

Relative density

About 0.94 at 25 °C.

Refractive index

About 1.448 at 25 °C.

IDENTIFICATION

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison   polyoxypropylene stearyl ether CRS.

B. Hydroxyl value (see Tests).
C. Saponification value (see Tests).
D. Viscosity (*2.2.9*): 83 mPa·s to 95 mPa·s.

TESTS

Acid value (*2.5.1*)

Maximum 2.0.

Hydroxyl value (*2.5.3, Method A*)

60 to 77.

Iodine value (*2.5.4, Method A*)

Maximum 3.0.

Peroxide value (*2.5.5, Method A*)

Maximum 5.0.

Saponification value (*2.5.6*)

Maximum 3.0.

Propylene oxide

Head-space gas chromatography (*2.2.28*).

Propylene oxide stock solution   Weigh 45 g of cold *macrogol 200 R1* and add 1.000 g (*m*) of *propylene oxide R*. Mix carefully by swirling to ensure a homogeneous solution. Add more *macrogol 200 R1* until the total weight is 50.0 g and mix again. [NOTE: the solution is stable for 1 month if stored at -20 °C]. Allow to reach room temperature. Dilute 0.50 g of this solution to 100.0 mL with *water R*.

Propylene oxide standard solution   Dilute 10.0 mL of propylene oxide stock solution to 100.0 mL with *water R*.

Propionaldehyde stock solution   Weigh 0.1 g of *propionaldehyde R* into a volumetric flask and dilute to 100.0 mL with *water R*.

Test solution (a)   Weigh 1.00 g of the substance to be examined into a 20 mL head-space vial. Add 0.5 mL of cold *water R* and seal the vial immediately with a polytetrafluoroethylene-coated silicon membrane and an aluminium cap. Mix carefully.

Test solution (b)   Weigh 1.00 g of the substance to be examined into a 20 mL head-space vial. Add 0.5 mL of cold propylene oxide standard solution and seal the vial immediately with a polytetrafluoroethylene-coated silicon membrane and an aluminium cap. Mix carefully.

Reference solution   Introduce 50.0 mL of cold propylene oxide standard solution into a volumetric flask, add 0.5 mL of cold propionaldehyde stock solution and dilute to 100.0 mL with *water R*. Introduce 0.5 mL of this solution into a 20 mL head-space vial.

Column:

— *material*: fused silica;

— *size*: *l* = 60 m, Ø = 0.32 mm;

— *stationary phase*: *methylpolysiloxane R* (film thickness 5 µm).

Carrier gas   *helium for chromatography R*.

Flow rate   2.6 mL/min.

Split ratio   10:1.

Static head-space conditions that may be used:

— *equilibration temperature*: 90 °C;

— *equilibration time*: 45 min.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 5	50
	5 - 31	50 → 180
	31 - 32.7	180 → 230
	32.7 - 37.7	230
Injection port		150
Detector		250

Detection   Flame ionisation.

Injection   A suitable volume, for example 1.0 mL, of the gaseous phase of test solutions (a) and (b) and of the reference solution.

Identification of peaks   Use the chromatogram obtained with the reference solution to identify the peaks due to propylene oxide and propionaldehyde.

Relative retention   With reference to propylene oxide (retention time = about 10.4 min): propionaldehyde = about 0.96.

System suitability   Reference solution:

— *resolution*: minimum 1.5 between the peaks due to propionaldehyde and propylene oxide;

— *signal-to-noise ratio*: minimum 10 for the peak due to propylene oxide.

Calculate the content of propylene oxide in parts per million using the following expression:

$$\frac{A_1 \times m \times 6}{(A_2 \times M_1) - (A_1 \times M_2)}$$

A_1	=	area of the peak due to propylene oxide in the chromatogram obtained with test solution (a);
A_2	=	area of the peak due to propylene oxide in the chromatogram obtained with test solution (b);
M_1	=	mass of the substance to be examined in test solution (a), in grams;
M_2	=	mass of the substance to be examined in test solution (b), in grams;
m	=	mass of propylene oxide used to prepare the propylene oxide stock solution, in grams.

Limit:

— *propylene oxide*: maximum 5 ppm.

Water (*2.5.12*)

Maximum 0.7 per cent, determined on 0.500 g.

Sulfated ash (*2.4.14*)

Maximum 0.3 per cent.

Ignite a suitable crucible at 600 ± 25 °C for 30 min, allow to cool in a desiccator over silica gel or other suitable desiccant and weigh. Place 1.0 g of the substance to be examined in the crucible and weigh. Carefully ignite and char the substance using a gas burner in a fume cupboard. Carry out the test for sulfated ash (*2.4.14*) on the residue obtained, starting from "Moisten the substance to be examined…".

STORAGE

In an airtight container.

LABELLING

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

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristic may be relevant for polyoxypropylene stearyl ether used as solvent or emollient in preparations for cutaneous application.

Viscosity

(see Identification).

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