



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

Propylene Glycol Monopalmitostearate



[General Notices](#)

Propylene Glycol Monostearate

(*Ph. Eur. monograph 1469*)

Action and use

Excipient.

Ph Eur

DEFINITION

Mixture of propylene glycol ((2*RS*)-propane-1,2-diol) mono- and diesters of palmitic (hexadecanoic) and stearic (octadecanoic) acids, produced by the condensation of propylene glycol and stearic acid 50 of vegetable or animal origin (see [Stearic acid \(1474\)](#)).

Content

Minimum 50.0 per cent of monoesters.

CHARACTERS

Appearance

White or almost white, waxy solid.

Solubility

Practically insoluble in water, soluble in acetone and in hot ethanol (96 per cent).

IDENTIFICATION

- A. Melting point (see Tests).
- B. Composition of fatty acids (see Tests).
- C. It complies with the assay (content of monoesters).

TESTS

Melting point ([2.2.15](#))

Acid value (2.5.1)

Maximum 4.0.

Iodine value (2.5.4)

Maximum 3.0.

Saponification value (2.5.6)

170 to 185, determined on 2.0 g.

Composition of fatty acids (2.4.22, Method A)

Composition of the fatty-acid fraction of the substance:

- *stearic acid*: 40.0 per cent to 60.0 per cent;
- *sum of contents of palmitic acid and stearic acid*: minimum 90.0 per cent.

Free propylene glycol

Maximum 5.0 per cent, determined as prescribed under Assay.

Water (2.5.12)

Maximum 1.0 per cent, determined on 1.00 g. Use a mixture of equal volumes of *methanol R* and *methylene chloride R* as the solvent.

Total ash (2.4.16)

Maximum 0.1 per cent.

ASSAY

Size-exclusion chromatography (2.2.30).

Test solution In a 15 mL flask, weigh 0.200 g (*m*). Add 5.0 mL of *tetrahydrofuran R* and shake to dissolve. Heat gently, if necessary. Reweigh the flask and calculate the total mass of solvent and substance (*M*).

Reference solutions In four 15 mL flasks, weigh respectively 2.5 mg, 5.0 mg, 10.0 mg and 20.0 mg of *propylene glycol R*. Add 5.0 mL of *tetrahydrofuran R* and shake to dissolve. Weigh the flasks again and calculate the concentration of propylene glycol in milligrams per gram for each reference solution.

Column:

- *size*: $l = 0.6$ m, $\varnothing = 7.5$ mm;
- *stationary phase*: *styrene-divinylbenzene copolymer R* (5 μ m) with a pore size of 10 nm.

Mobile phase *tetrahydrofuran R*.

Flow rate 1 mL/min.

Detection Differential refractometer.

Injection 40 μ L.

Relative retention With reference to propylene glycol: diesters = about 0.78; monoesters = about 0.84.

Calculations:

— *free propylene glycol*: from the calibration curve obtained with the reference solutions, determine the concentration of propylene glycol (*C*) in milligrams per gram in the test solution and calculate the percentage content of free propylene glycol (*A*) in the substance to be examined using the following expression:

— *free fatty acids*: calculate the percentage content of free fatty acids (*D*) using the following expression:

- I_A = acid value (see Tests);
- 270 = average rounded molar mass of palmitic acid and stearic acid, in grams per mole;
- 56.11 = molar mass of potassium hydroxide, in grams per mole.

— *monoesters*: calculate the percentage content of monoesters using the following expression:

- A* = percentage content of free propylene glycol;
- B* = percentage content of water (see Tests);
- D* = percentage content of free fatty acids;
- X* = area of the peak due to monoesters and free fatty acids;
- Y* = area of the peak due to diesters.

STORAGE

Protected from light.

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