



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

## Glycerol Distearate



### [General Notices](#)

(Ph. Eur. monograph 1428)

### Action and use

Excipient.

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## DEFINITION

Mixture of diacylglycerols, mainly distearoylglycerol, together with variable quantities of mono- and triacylglycerols. It is obtained by partial glycerolysis of vegetable oils containing triacylglycerols of palmitic (hexadecanoic) and stearic (octadecanoic) acids or by esterification of glycerol with stearic acid. The fatty acids may be of vegetable or animal origin.

### Content

- *monoacylglycerols*: 8.0 per cent to 22.0 per cent;
- *diacylglycerols*: 40.0 per cent to 60.0 per cent;
- *triacylglycerols*: 25.0 per cent to 35.0 per cent.

## CHARACTERS

### Appearance

Hard, waxy mass or powder, or white or almost white, unctuous flakes.

### Solubility

Practically insoluble in water, soluble in methylene chloride, partly soluble in hot ethanol (96 per cent).

## IDENTIFICATION

- Melting point ([2.2.14](#)): 50 °C to 60 °C (types I and II), 50 °C to 70 °C (type III).
- Composition of fatty acids (see Tests) according to the type stated on the label.
- It complies with the limits of the assay (diacylglycerol content).

## TESTS

**Acid value** (2.5.1)

Maximum 6.0, determined on 1.0 g.

Use a mixture of equal volumes of [ethanol \(96 per cent\) R](#) and [toluene R](#) as solvent and heat gently.

**Iodine value** (2.5.4, Method A)

Maximum 3.0.

**Saponification value** (2.5.6)

165 to 195, determined on 2.0 g. Carry out the titration with heating.

**Free glycerol**

Maximum 1.0 per cent, determined as described under Assay.

**Composition of fatty acids** (2.4.22, Method C)

Use the mixture of calibrating substances in Table 2.4.22.-1.

*Composition of the fatty-acid fraction of the substance:*

Glycerol distearate	Composition of fatty acids
Type I	<a href="#">Stearic acid</a> : 40.0 per cent to 60.0 per cent <i>Sum of the contents of palmitic and stearic acids</i> : minimum 90.0 per cent
Type II	<a href="#">Stearic acid</a> : 60.0 per cent to 80.0 per cent <i>Sum of the contents of palmitic and stearic acids</i> : minimum 90.0 per cent
Type III	<a href="#">Stearic acid</a> : 80.0 per cent to 99.0 per cent <i>Sum of the contents of palmitic and stearic acids</i> : minimum 96.0 per cent

**Water** (2.5.12)

Maximum 1.0 per cent, determined on 1.00 g. Use [pyridine R](#) as the solvent.

**Total ash** (2.4.16)

Maximum 0.1 per cent.

**ASSAY**

Size-exclusion chromatography (2.2.30).

*Test solution* Into a 15 mL flask, weigh 0.200 g (*m*) of the substance to be examined. Add 5.0 mL of [tetrahydrofuran R](#) and shake to dissolve. Reweigh the flask and calculate the total mass of solvent and substance (*M*).

*Reference solutions* Into three 15 mL flasks, respectively weigh 2.0 mg, 5.0 mg and 10.0 mg of [glycerol R](#) and add 5.0 mL of [tetrahydrofuran R](#) to each flask. Into a 4<sup>th</sup> flask, weigh 2.0 mg of [glycerol R](#) and add 10.0 mL of [tetrahydrofuran R](#). Weigh the flasks again and calculate the concentration of glycerol in milligrams per gram for each reference solution.

*Column:*

- *size*: *l* = 0.6 m, Ø = 7 mm;
- *stationary phase*: [styrene-divinylbenzene copolymer R](#) (5 µm) with a pore size of 10 nm.

Flow rate 1 mL/min.

Detection Differential refractometer.

Injection 40 µL.

**Relative retention** With reference to glycerol (retention time = about 15 min): triacylglycerols = about 0.75; diacylglycerols = about 0.80; monoacylglycerols and free fatty acids = about 0.85.

**Calculations:**

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

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

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$I_A$  = acid value;

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

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*B* = percentage content of water (see Tests);

*X* = area of the peak due to monoacylglycerols and free fatty acids;

*Y* = area of the peak due to diacylglycerols;

*Z* = area of the peak due to triacylglycerols;

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

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

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## LABELLING

The label states the type of glycerol distearate.

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