



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

Oleoyl Macroglycerides



[General Notices](#)

(Ph. Eur. monograph 1249)

Action and use

Excipient.

Ph Eur

DEFINITION

Mixtures of monoesters, diesters and triesters of glycerol and monoesters and diesters of macrogols.

They are obtained by partial alcoholysis of an unsaturated oil mainly containing triglycerides of oleic ((9Z)-octadec-9-enoic) acid, using macrogol with a mean relative molecular mass between 300 and 400, or by esterification of glycerol and macrogol with unsaturated fatty acids, or by mixing glycerol esters and condensates of ethylene oxide with the fatty acids of this unsaturated oil.

CHARACTERS

Appearance

Amber oily liquid, which may give rise to a deposit after prolonged periods at 20 °C.

Solubility

Practically insoluble but dispersible in water, freely soluble in methylene chloride.

[Relative density](#)

About 0.95 at 20 °C.

[Refractive index](#)

About 1.47 at 20 °C.

[Viscosity](#)

About 35 mPa·s at 40 °C.

IDENTIFICATION

A. Thin-layer chromatography ([2.2.27](#)).

Test solution Dissolve 1.0 g of the substance to be examined in [methylene chloride R](#) and dilute to 20 mL with the same solvent.

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

Mobile phase [hexane R](#), [ether R](#) (30:70 V/V).

Application 10 µL.

Development Over a path of 15 cm.

Drying In air.

Detection Spray with a 0.1 g/L solution of [rhodamine B R](#) in [ethanol \(96 per cent\) R](#) and examine in ultraviolet light at 365 nm.

Results The chromatogram shows a spot due to triglycerides with an R_F value of about 0.9 (R_{st} 1) and spots due to 1,3-diglycerides (R_{st} 0.7), to 1,2-diglycerides (R_{st} 0.6), to monoglycerides (R_{st} 0.1) and to esters of macrogol (R_{st} 0).

B. Hydroxyl value (see Tests).

C. Saponification value (see Tests).

D. Composition of fatty acids (see Tests).

TESTS

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

Maximum 2.0, determined on 2.0 g.

[Hydroxyl value \(2.5.3, Method A\)](#)

45 to 65, determined on 1.0 g.

[Iodine value \(2.5.4, Method A\)](#)

75 to 95.

[Peroxide value \(2.5.5, Method A\)](#)

Maximum 12.0, determined on 2.0 g.

[Saponification value \(2.5.6\)](#)

150 to 170, determined on 2.0 g.

Alkaline impurities

Introduce 5.0 g into a test tube and carefully add a mixture, neutralised if necessary with [0.01 M hydrochloric acid](#) or with [0.01 M sodium hydroxide](#), of 0.05 mL of a 0.4 g/L solution of [bromophenol blue R](#) in [ethanol \(96 per cent\) R](#), 0.3 mL of [water R](#) and 10 mL of [ethanol \(96 per cent\) R](#). Shake and allow to stand. Not more than 1.0 mL of [0.01 M hydrochloric acid](#) is required to change the colour of the upper layer to yellow.

Free glycerol

Maximum 3.0 per cent.

Dissolve 1.20 g in 25.0 mL of [methylene chloride R](#). Heat if necessary. After cooling, add 100 mL of [water R](#). Shake and add 25.0 mL of [periodic acetic acid solution R](#). Shake and allow to stand for 30 min. Add 40 mL of a 75 g/L solution of [potassium iodide R](#). Allow to stand for 1 min. Add 1 mL of [starch solution R](#). Titrate the iodine with [0.1 M sodium thiosulfate](#). Carry out a blank titration.

1 mL of [0.1 M sodium thiosulfate](#) is equivalent to 2.3 mg of glycerol.

Composition of fatty acids (2.4.22, Method A)

Composition of the fatty-acid fraction of the substance:

- [palmitic acid](#): 4.0 per cent to 9.0 per cent;
- [stearic acid](#): maximum 6.0 per cent;
- [oleic acid](#): 58.0 per cent to 80.0 per cent;
- [linoleic acid](#): 15.0 per cent to 35.0 per cent;
- [linolenic acid](#): maximum 2.0 per cent;
- [arachidic acid](#): maximum 2.0 per cent;
- [eicosenoic acid](#): maximum 2.0 per cent.

Ethylene oxide and dioxan (2.4.25)

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

Water (2.5.12)

Maximum 1.0 per cent, determined on 1.00 g. Use a mixture of 30 volumes of [anhydrous methanol R](#) and 70 volumes of [methylene chloride R](#) as solvent.

Total ash (2.4.16)

Maximum 0.1 per cent.

STORAGE

Protected from light.

LABELLING

The label states the type of macrogol used (mean relative molecular mass) or the number of units of ethylene oxide per molecule (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 characteristics may be relevant for oleoyl macrogolglycerides used as self-emulsifying agents and solubilisers.

Hydroxyl value

(see Tests).

Saponification value

(see Tests).

Composition of fatty acids

(see Tests).

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