



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

Refined Evening Primrose Oil



[General Notices](#)

(Ph. Eur. monograph 2104)

Ph Eur

DEFINITION

Fatty oil obtained from seeds of *Oenothera biennis* L. or *Oenothera lamarckiana* L. by extraction and/or expression. It is then refined. A suitable antioxidant may be added.

PRODUCTION

The oil is prepared using materials and methods designed to ensure that the content of brassicasterol ([2.4.23](#)) in the sterol fraction of the oil is not greater than 0.3 per cent.

CHARACTERS

Appearance

Clear, light yellow or yellow liquid.

Solubility

Practically insoluble in water and in ethanol (96 per cent), miscible with light petroleum (bp: 40-60 °C).

[Relative density](#)

About 0.923.

[Refractive index](#)

About 1.478.

IDENTIFICATION

First identification: B.

Second identification: A.

A. Identification of fatty oils by thin-layer chromatography ([2.3.2](#)).

Results The chromatogram obtained is similar to the corresponding chromatogram shown in Figure 2.3.2.-1.

B. Composition of fatty acids (see Tests).

TESTS

Acid value (2.5.1)

Maximum 0.5, or maximum 0.3 if intended for use in the manufacture of parenteral preparations.

Peroxide value (2.5.5, Method A)

Maximum 10.0, or maximum 5.0 if intended for use in the manufacture of parenteral preparations.

Unsaponifiable matter (2.5.7)

Maximum 2.5 per cent, determined on 5.0 g.

Alkaline impurities (2.4.19)

It complies with the test.

Composition of fatty acids (2.4.22, Method A)

Use the mixture of calibrating substances in Table 2.4.22.-3.

Composition of the fatty-acid fraction of the oil:

- *saturated fatty acids of chain length less than C₁₆*: maximum 0.3 per cent;
- *palmitic acid*: 4.0 per cent to 10.0 per cent;
- *stearic acid*: 1.0 per cent to 4.0 per cent;
- *oleic acid*: 5.0 per cent to 12.0 per cent;
- *linoleic acid*: 65.0 per cent to 85.0 per cent;
- *gamma-linolenic acid*: 7.0 per cent to 14.0 per cent;
- *alpha-linolenic acid*: maximum 0.5 per cent.

Water (2.5.32)

Maximum 0.1 per cent, determined on 1.00 g.

STORAGE

Under an inert gas, in a well-filled, airtight container, protected from light.

LABELLING

The label states:

- where applicable, that the oil is suitable for use in the manufacture of parenteral preparations;
- the name of the inert gas.

