



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

Refined Safflower Oil



General Notices

(Ph. Eur. monograph 2088)

Ph Eur

DEFINITION

Fatty oil obtained from seeds of *Carthamus tinctorius* L. (type I) or from seeds of hybrids of *Carthamus tinctorius* L. (type II), by expression and/or extraction followed by refining. Type II refined safflower oil is rich in oleic ((9Z)-octadec-9-enoic) acid. 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, viscous, yellow or pale yellow liquid.

Solubility

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

	Type I refined safflower oil	Type II refined safflower oil
Relative density	about 0.922	about 0.914
Refractive index	about 1.476	about 1.472

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 for type I or type II shown in Figure 2.3.2.-1.

TESTS

Acid value (2.5.1)

Maximum 0.5.

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 1.5 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 type I refined safflower oil:

- *saturated fatty acids of chain length less than C14*: maximum 0.2 per cent;
- *myristic acid*: maximum 0.2 per cent;
- *palmitic acid*: 4.0 per cent to 10.0 per cent;
- *stearic acid*: 1.0 per cent to 5.0 per cent;
- *oleic acid*: 8.0 per cent to 21.0 per cent;
- *linoleic acid*: 68.0 per cent to 83.0 per cent;
- *linolenic acid*: maximum 0.5 per cent;
- *arachidic acid*: maximum 0.5 per cent;
- *eicosenoic acid*: maximum 0.5 per cent;
- *behenic acid*: maximum 1.0 per cent.

Composition of the fatty-acid fraction of type II refined safflower oil:

- *saturated fatty acids of chain length less than C14*: maximum 0.2 per cent;
- *myristic acid*: maximum 0.2 per cent;
- *palmitic acid*: 3.6 per cent to 6.0 per cent;
- *stearic acid*: 1.0 per cent to 5.0 per cent;
- *oleic acid*: 70.0 per cent to 84.0 per cent;
- *linoleic acid*: 7.0 per cent to 23.0 per cent;
- *linolenic acid*: maximum 0.5 per cent;
- *arachidic acid*: maximum 1.0 per cent;
- *eicosenoic acid*: maximum 1.0 per cent;

Water (2.5.32)

Maximum 0.1 per cent, determined on 1.00 g.

STORAGE

In a well-filled, airtight container, protected from light.

LABELLING

The label states:

- where applicable, that the substance is suitable for use in the manufacture of parenteral preparations;
- the type of oil (type I or type II).

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