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Refined Wheat-germ Oil

General Notices

(Ph. Eur. monograph 1379)

Ph Eur

DEFINITION

Fatty oil obtained from the germ of the grain of *Triticum aestivum* L. by cold expression or by other suitable mechanical means and/or by extraction. 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 liquid.

Solubility

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

Relative density

About 0.925.

Refractive index

About 1.475.

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 0.9, 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 5.0 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 C*)

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

Composition of the fatty-acid fraction of the oil:

— *palmitic acid*: 14.0 per cent to 19.0 per cent;

— *stearic acid*: maximum 2.0 per cent;

— *oleic acid*: 12.0 per cent to 23.0 per cent;

— *linoleic acid*: 52.0 per cent to 59.0 per cent;

— *linolenic acid*: 3.0 per cent to 10.0 per cent;

— *eicosenoic acid*: maximum 2.0 per cent.

Water (*2.5.32*)

Maximum 0.1 per cent, determined on 1.00 g.

STORAGE

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

LABELLING

The label states:

— where applicable, that the substance is suitable for use in the manufacture of parenteral preparations;

— whether the oil is obtained by mechanical means, by extraction or by a combination of the 2.