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21 Author

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22 Date of Revision

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Safflower Oil

1 Nonproprietary Names

BP: Refined Safflower Oil

PhEur: Safflower Oil, Refined

USP-NF: Safflower Oil

2 Synonyms

Aceite de alazor; aceite de cartamo; carthami oleum raffinatum; dygminu aliejus, rafinuotas; huile de carthame; safflorolja, raffinerad; safflower oil (unhydrogenated); saflonoljy puhdistettu.

3 Chemical Name and CAS Registry Number

Safflower oil [8001-23-8]

4 Empirical Formula and Molecular Weight

The PhEur 9.2 defines the composition of the fatty acid fraction of two types of refined safflower oil (type I and type II); see Section 9.

5 Structural Formula

See Section 4.

6 Functional Category

Emollient; oleaginous vehicle; solvent.

7 Applications in Pharmaceutical Formulation or Technology

Safflower oil is mainly used as an oleaginous vehicle in oral and topical formulations.

Safflower oil has been used as a vehicle in the development of an oral dosage form containing a novel viral-specific inhibitor of the replication of human rhinoviruses.⁽¹⁾ It has also been used as a solvent for a capsule formulation containing a new antilipemic agent; formulations containing safflower oil were found to have the

greatest bioavailability in dogs compared with formulations containing PEG 300 or water.⁽²⁾

Safflower oil is used in cosmetics products such as soaps, lotions, creams, and hair-care preparations.

8 Description

Refined safflower oil is a clear, viscous, yellow to pale-yellow liquid, with a slight vegetable odor.

9 Pharmacopeial Specifications

See Table I. See also Section 18.

The PhEur 9.2 defines the composition of the fatty acid fraction, refractive index, and relative density values of two types of refined safflower oil (type I and type II); see Tables II and III.

Table I: Pharmacopeial specifications for safflower oil.

Test	PhEur 9.2	USP 40-NF 35 S1
Identification	+	---
Characters	+	-
Acid value	≤0.5	-
Peroxide value	≤10.0 ^(a)	≤10
Unsaponifiable matter	≤1.5%	≤1.5%
Alkaline impurities	+	-
Composition of fatty acids	+ ^(b)	+
Brassicasterol	≤0.3% in sterol fraction of oil	-
Water	≤0.1%	-
Free fatty acids	-	+
Iodine value	-	135-150
Heavy metals	-	≤10 ppm

(a) ≤5.0 if for parenteral use.

(b) Compositions of the fatty acid fraction of type I and type II refined safflower oil are defined.