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Safflower Oil

CAS RN®: 8001-23-8.

DEFINITION

Safflower Oil is the refined fixed oil yielded by the seed of *Carthamus tinctorius* L. (Fam. Compositae). A suitable antioxidant may be added.

IDENTIFICATION

• **A. Identity by Fatty Acid Composition**

Analysis: Proceed as directed in the test for *Fats and Fixed Oils ⟨401⟩, Fatty Acid Composition*.

Acceptance criteria: Meets the composition profile of fatty acids in *Table 1*

• **B. Identity by Triglyceride Profile**

Analysis: Proceed as directed in *Identification of Fixed Oils by Thin-Layer Chromatography ⟨202⟩*.

Acceptance criteria: Meets the requirements in the chapter

IMPURITIES

• **Alkaline Impurities**

Sample: 10 mL of Safflower Oil

Analysis: Mix 10 mL of freshly opened acetone and 0.3 mL of water, and add 0.05 mL of bromophenol blue TS. Add the *Sample*, shake, and allow to stand. Titrate with 0.01 N hydrochloric acid VS to change the color of the upper layer to yellow.

Acceptance criteria: NMT 0.1 mL of 0.01 N hydrochloric acid is required.

SPECIFIC TESTS

• **Fats and Fixed Oils,** *Acid Value (Free Fatty Acids) ⟨401⟩*: The free fatty acids in 10 g require for neutralization NMT 2.5 mL of 0.020 N sodium hydroxide.

• **Fats and Fixed Oils,** *Fatty Acid Composition ⟨401⟩*

Standard solution, System suitability solution, Chromatographic system, and **System suitability:** Proceed as directed in *Fats and Fixed Oils ⟨401⟩, Fatty Acid Composition*.

1 N methanolic potassium hydroxide solution: Dissolve 34 g of potassium hydroxide in sufficient methanol to produce 500 mL. Allow to settle for 24 h, and decant the clear solution.

Sample solution: Place 1 g of Safflower Oil in a small conical flask fitted with a reflux attachment. Add 10 mL of methanol and 0.5 mL of *1 N methanolic potassium hydroxide solution*. Reflux the mixture for 10 min, cool, and transfer to a separator with the aid of 15 mL of *n*-heptane. Shake with 10 mL of saturated sodium chloride solution, and allow to separate. Transfer the lower layer to another separator, and shake it with 10 mL of *n*-heptane. Wash the combined organic layers with 10 mL of water, dry over anhydrous sodium sulfate, and filter. Use a suitable portion of the filtrate.

Analysis: Inject a suitable volume into the chromatograph, and measure the nine main peak areas of the methyl esters of the fatty acids. The order of elution is myristate, palmitate, stearate, oleate, linoleate, linolenate, arachidate, eicosenoate, and behenate.

Calculate the percentage of myristate, palmitate, stearate, oleate, linoleate, linolenate, arachidate, eicosenoate, or behenate in the portion of Safflower Oil taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of myristate, palmitate, stearate, oleate, linoleate, linolenate, arachidate, eicosenoate, or behenate

r_T = total area of the nine peaks

Acceptance criteria: It exhibits the composition profiles of fatty acids shown in *Table 1*.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
14	0	≤1.0
16	0	2–10
18	0	1–10
18	1	8–21
18	2	68–83
18	3	≤1.5
20	0	≤0.5
20	1	≤0.5
22	0	≤1.0

- **Fats and Fixed Oils,** *Unsaponifiable Matter* ⟨401⟩**:** NMT 1.5%
- **Limit of Peroxide**

Solvent A: Chloroform and glacial acetic acid (40:60)

Potassium iodide solution: Prepare a saturated solution of potassium iodide in freshly boiled and cooled water, and store it protected from light. Discard the solution if it gives a color on the addition of *Solvent A* and starch TS.

Sample: 10 g of Safflower Oil

Analysis: Transfer the *Sample* to a conical flask, add 30 mL of *Solvent A*, and swirl to dissolve. Add 0.5 mL of *Potassium iodide solution*, and swirl the flask for 1 min, accurately timed. Add 30 mL of water, and titrate with 0.01 N sodium thiosulfate VS, with vigorous agitation, to a light yellow color. Add 0.5 mL of starch TS, and continue the titration until the blue color has disappeared. Perform a blank test, and make any necessary correction.

Calculate the peroxide content, in mEq/kg, in the portion of Safflower Oil taken:

$$\text{Result} = [(V \times N)/W] \times F$$

V = volume of sodium thiosulfate required in the titration (mL)

N = normality of the sodium thiosulfate VS

W = weight of Safflower Oil taken (g)

F = conversion factor, 1000 g/kg

Acceptance criteria: NMT 10.0 mEq/kg

- **Water Determination,** *Method Ic* ⟨921⟩**:** NMT 0.1%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, and prevent exposure to excessive heat.
- **Labeling:** Label it to indicate the name and concentration of any additive.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SAFFLOWER OIL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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