Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: NF Monographs
DocId: GUID-71E9F809-E4C0-4410-8635-E5966B2089D9_3_en-US
DOI: https://doi.org/10.31003/USPNF_M80110_03_01
DOI Ref: v9f8g

Sunflower Oil

CAS RN®: 8001-21-6.

DEFINITION

Sunflower Oil is a refined fixed oil obtained from the seeds of the sunflower plant *Helianthus annuus* L. (Fam. Asteraceae alt. Compositae). It may contain a suitable antioxidant.

IDENTIFICATION

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

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

  Acceptance criteria: It meets the composition profile of fatty acids in *Table 2*.

- **B. Identity by Triglyceride Profile**

  Analysis: Perform this test for generic oil only. Proceed as directed in *Identification of Fixed Oils by Thin-Layer Chromatography* ⟨202⟩.

  Acceptance criteria: It meets the requirements in the chapter.

IMPURITIES

- **Alkaline Impurities**

  Sample: 10 mL of Sunflower 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⟩**:** NMT 2.5 mL of 0.020 N sodium hydroxide is required for neutralization.

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

  Standard solution: Prepare an ester mixture containing methyl linoleate, methyl oleate, methyl palmitate, methyl stearate, and methyl linolenate (50:35:7:5:3).[1]

  Sample solution: Transfer 100 mg of Sunflower Oil to a 50-mL conical flask fitted with a suitable water-cooled reflux condenser and a magnetic stir bar. Add 4 mL of 0.5 N methanolic sodium hydroxide solution, and reflux until fat globules disappear (usually 5–10 min). Add 5 mL of a solution prepared by dissolving 14 g of boron trifluoride in methanol to make 100 mL, swirl to mix, and reflux for 2 min. Add 4 mL of chromatographic *n*-heptane through the condenser, and reflux for 1 min. Cool, remove the condenser, add 15 mL of saturated sodium chloride solution, shake, and allow the layers to separate. Pass the *n*-heptane layer through 0.1 g of anhydrous sodium sulfate (previously washed with chromatographic *n*-heptane) into a suitable flask. Transfer 1.0 mL of this solution to a 10-mL volumetric flask, dilute with chromatographic *n*-heptane to volume, and mix.

  Chromatographic system

  (See *Chromatography* ⟨621⟩, *System Suitability*.)

  Mode: GC

  Detector: Flame ionization

  Column: 0.25-mm × 30-m fused-silica capillary column bonded with a 0.25-µm layer of phase G5

  Temperatures

  Injector: 220°

  Detector: 250°

  Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
120	—	120	2
120	4	240	5

Carrier gas: Hydrogen

Flow rate: 1 mL/min

Injection volume: 1 µL

Injection type: Splitless

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for methyl palmitate, methyl stearate, and methyl oleate are about 0.87, 0.99, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between methyl stearate and methyl oleate

Relative standard deviation: NMT 6.0% peak areas for the palmitate and stearate peaks for replicate injections; NMT 1.0% peak area ratio of the palmitate to stearate peaks from these replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Measure the areas of the five major peaks for the methyl esters of the fatty acids, which elute in the following order: palmitate, stearate, oleate, linoleate, and linolenate.

Calculate the percentage of palmitate, stearate, oleate, linoleate, and linolenate in the portion of Sunflower Oil taken:

$$\text{Result} = (A/B) \times 100$$

A = peak area of palmitate, stearate, oleate, linoleate, or linolenate

B = total area of the five major peaks

Acceptance criteria: See *Table 2*.

Table 2

	Generic Oil (%)	Mid-Oleic Oil (%)	High-Oleic Oil (%)
Methyl palmitate	3–10	2–9	2–9
Methyl stearate	2–8	2–8	2–8
Methyl oleate	14–39	40–70	70–90
Methyl linoleate	48–73	15–40	5–15
Methyl linolenate	0–3	0–3	0–3

• **FATS AND FIXED OILS,** *Iodine Value, Method II* ⟨401⟩

Acceptance criteria

Generic oil: 128–148

Mid-oleic oil: 98–118

High-oleic oil: 78–98

• **FATS AND FIXED OILS,** *Unsaponifiable Matter* ⟨401⟩**:** NMT 1.0%

• **LIMIT OF PEROXIDE**

[NOTE—This test must be performed promptly after sampling to avoid oxidation of the test specimen.]

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 protected from light. Discard the solution if it becomes colored upon the addition of *Solvent A* and iodide-free starch TS.

Sample: 10 g of Sunflower 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*, swirl for 1.0 min, and add 30 mL of water. Titrate with 0.01 N sodium thiosulfate VS, with vigorous agitation, to a light yellow color. Add 2.0 mL of iodide-free starch TS, and continue the titration until the blue color has disappeared. Perform a blank determination, and make any necessary correction.

Calculate the amount of peroxide, in mEq/kg, in the portion of Sunflower Oil taken:

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

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

N = normality of sodium thiosulfate VS (mEq/mL)

W = weight of Sunflower 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. No storage requirement specified.

• **Labeling:** The label states the Latin binomial and, following the official name, the part of the plant source from which the article was derived. Label it to indicate whether it is Generic Sunflower Oil, Mid-Oleic Sunflower Oil, or High-Oleic Sunflower Oil. The label also indicates the name and concentration of any additive.

[1] Ester mixtures are available commercially from Nu-Chek-Prep, Inc., P.O. Box 295, Elysian, MN 56028. Typical Nu-Chek-Prep ester mixtures useful in this test include Nu-Chek 15A. This mixture may contain other components.

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(5)

Current DocID: GUID-71E9F809-E4C0-4410-8635-E5966B2089D9_3_en-US
Previous DocID: GUID-71E9F809-E4C0-4410-8635-E5966B2089D9_1_en-US
DOI: https://doi.org/10.31003/USPNF_M80110_03_01
DOI ref: v9f8g