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Sesame Oil

DEFINITION

Sesame Oil is the refined fixed oil obtained from the seed of one or more cultivated varieties of *Sesamum indicum* L. (Fam. Pedaliaceae). It may contain suitable antioxidants.

IDENTIFICATION

• **A. Identity by Triglyceride Profile**

Analysis: Proceed as directed in the test for *Triglyceride Composition*.

Acceptance criteria: The peak responses of the eight major triglycerides—LLL, OLL, PLL, OOL, POL, OOO, SOL, and POO—elute between 0 and about 40 min, in the order specified, and at relative retention times of about 0.55, 0.65, 0.69, 0.77, 0.82, 0.93, 0.97, and 1.0, respectively, as obtained in the *Sample solution* in the test for *Triglyceride Composition*.

ASSAY

• **Triglyceride Composition**

[Note—The fatty acid radicals are designated as linoleic (L), oleic (O), palmitic (P), and stearic (S), and the common abbreviations for triglycerides used are as follows: trilinolein (LLL), 1,2-dilinoleoyl-3-oleoyl-rac-glycerol (OLL), 1,2-dilinoleoyl-3-palmitoyl-rac-glycerol (PLL), 1,2-dioleoyl-3-linoleoyl-rac-glycerol (OOL), 1-palmitoyl-2-oleoyl-3-linoleoyl-rac-glycerol (POL), triolein (OOO), 1-linoleoyl-2-oleoyl-3-stearoyl-rac-glycerol (SOL), and 1,2-dioleoyl-3-palmitoyl-rac-glycerol (POO).]

Mobile phase: Acetonitrile and methylene chloride (60:40)

System suitability solution: 3.0 mg/mL each of USP Sesame Oil Related Compound A RS and USP Sesame Oil Related Compound B RS in *Mobile phase*. [Note—USP Sesame Oil Related Compound A RS is OLL, and USP Sesame Oil Related Compound B RS is PLL.]

Sample solution: 20 mg/mL of Sesame Oil in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: Refractive index

Columns: Two 4.6-mm × 25-cm in series; packings L1

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for OLL and PLL are about 0.93 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.8 between OLL and PLL

Relative standard deviation: NMT 1.5% determined from peak areas; NMT 2.2% determined from the peak area ratio of OLL to PLL

Analysis

[Note—The relative retention times for the eight major triglyceride peaks are listed in *Table 1*.]

Sample: *Sample solution*

Calculate the percentage of each of these triglycerides in the portion of the *Sample* taken:

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

A = peak area of each individual triglyceride

B = sum of the areas of all the peaks, excluding the solvent peak

Table 1

Triglyceride	Relative Retention Time	Composition (%)
LLL	0.55	7.0–19.0
OLL	0.65	13.0–30.0
PLL	0.69	5.0–9.0
OOL	0.77	14.0–25.0
POL	0.82	8.0–16.0
OOO	0.93	5.0–14.0
SOL	0.97	2.0–8.0
POO	1.0	2.0–8.0

IMPURITIES

• **Alkaline Impurities**

Sample: 10 mL of Sesame 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

• **Specific Gravity ⟨841⟩:** 0.912–0.921

• **Fats and Fixed Oils ⟨401⟩, *Acid Value (Free Fatty Acids)***

Sample: 10 g

Acceptance criteria: NMT 2.0 mL of 0.020 N sodium hydroxide is required for neutralization.

• **Fats and Fixed Oils ⟨401⟩, *Iodine Value*:** 103–116

• **Fats and Fixed Oils ⟨401⟩, *Saponification Value*:** 188–195

• **Fats and Fixed Oils ⟨401⟩, *Solidification Temperature of Fatty Acids*:** 20°–25°

• **Fats and Fixed Oils, *Peroxide Value* ⟨401⟩:** NMT 10.0

• **Fats and Fixed Oils ⟨401⟩, *Unsaponifiable Matter*:** NMT 1.5%

• **Cottonseed Oil**

Sample: 5 mL

Analysis: Mix the *Sample* in a test tube with 5 mL of a mixture of equal volumes of amyl alcohol and a 10-mg/mL solution of sulfur in carbon disulfide. Warm the mixture carefully until the carbon disulfide is expelled, and immerse the tube to one-third of its depth in a boiling saturated solution of sodium chloride.

Acceptance criteria: No reddish color develops within 15 min.

• **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 quantity of any added antioxidant. Where Sesame Oil is intended for use in the manufacture of injectable dosage forms, it is so labeled.

• **Other Requirements:** For Sesame Oil intended for use in injectable dosage forms, which is specified in the labeling, the requirements must be met for *Unsaponifiable Matter*, *Acid Value*, *Peroxide Value*, and *Water*, *Method Ic*, under *Specific Tests* in *Injections and Implanted Drug Products ⟨1⟩, Vehicles and added substances, Nonaqueous vehicles*.

- **USP Reference Standards ⟨11⟩**

USP Sesame Oil Related Compound A RS
USP Sesame Oil Related Compound B RS

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

Topic/Question	Contact	Expert Committee
SESAME 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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