

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

Delete the following:

- **HEAVY METALS, Method II <231>:** NMT 10 µg/g • (Official 1-Dec-2015)

SPECIFIC TESTS

Change to read:

- **SPECIFIC GRAVITY <841>:** • 0.912 • (IRA 1-Jul-2015)–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 <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.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and prevent exposure to excessive heat.

Change to read:

- **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. • (IRA 1-Jul-2015)

2 Sesame

Add the following:

- **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 the chapter *Injections and Implanted Drug Products* (1), *Vehicles and added substances, Nonaqueous vehicles*. ● (IRA 1-Jul-2015)

- **USP REFERENCE STANDARDS** (11)
 - USP Sesame Oil Related Compound A RS
 - USP Sesame Oil Related Compound B RS