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Cottonseed Oil

CAS RN®: 8001-29-4.

DEFINITION

Cottonseed Oil is the refined fixed oil obtained from the seed of cultivated plants of various varieties of *Gossypium hirsutum* L. or of other species of *Gossypium* (Fam. Malvaceae). It may contain suitable antioxidants.

IDENTIFICATION

• **A. IDENTITY BY FATTY ACID COMPOSITION:** Cottonseed Oil exhibits the composition profile of fatty acids, as determined in [Fats and Fixed Oils \(401\), Procedures, Fatty Acid Composition](#). See [Table 1](#).

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
<14	0 or 1	≤0.2
14	0	0.3–1.0
16	0	18.0–26.4
16	1	≤1.2
18	0	2.1–3.3
18	1	14.0–21.7
18	2	46.7–58.3
18	3	≤1.0
20	0	≤1.0
20	1	≤0.5
22	0	≤0.6
22	1	≤0.5
24	0	≤0.5

• **B. IDENTITY BY TRIGLYCERIDE PROFILE**

Analysis: Proceed as directed in [Identification of Fixed Oils by Thin-Layer Chromatography \(202\)](#), [Identification, Method I](#) or [Method II](#).
Acceptance criteria: Meets the requirements in the chapter

IMPURITIES

• **ALKALINE IMPURITIES**

Sample: 10 mL of Cottonseed Oil

Analysis: Mix 10 mL of acetone and 0.3 mL of water, and add 0.05 mL of bromophenol blue TS. If necessary, neutralize the solution to a green color with 0.01 N hydrochloric acid or 0.01 N sodium hydroxide. 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** (401), *Procedures, Acid Value*: NMT 0.2
- **FATS AND FIXED OILS** (401), *Procedures, Peroxide Value*: NMT 10.0
- **FATS AND FIXED OILS** (401), *Procedures, Unsaponifiable Matter*: NMT 1.5%
- **WATER DETERMINATION** (921), *Method I, Method Ic*: NMT 0.1%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.
- **LABELING:** Label it to indicate the name and quantity of any added antioxidants. Where Cottonseed Oil is intended for use in the manufacture of injectable dosage forms, it is so labeled.
- **OTHER REQUIREMENTS:** For Cottonseed Oil intended for use in injectable dosage forms, which is specified in the *Labeling* section, the requirements under *Injections and Implanted Drug Products (1), Product Quality Tests Common to Parenteral Dosage Forms, Specific Tests, Vehicles and added substances, Nonaqueous vehicles* must be met.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
COTTONSEED OIL	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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