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Corn Oil

CAS RN[®]: 8001-30-7.

DEFINITION

Corn Oil is the refined fixed oil obtained from the embryo of *Zea mays* L. (Fam. Gramineae).

IDENTIFICATION

• **A. IDENTITY BY FATTY ACID COMPOSITION**

Analysis: Proceed as directed in the test for [Fats and Fixed Oils \(401\)](#), [Procedures](#), [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 \(202\)](#), [Identification, Method I](#) or [Method II](#).

Acceptance criteria: Meets the requirements in the chapter

IMPURITIES

• **ALKALINE IMPURITIES**

Sample: 10 mL of Corn Oil

Analysis: Mix 10 mL of acetone and 0.3 mL of water, and add 0.05 mL of bromophenol blue TS. Neutralize the solution to a green color if necessary 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](#), [Fatty Acid Composition](#): Corn Oil exhibits the composition profile of fatty acids in [Table 1](#).

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
<14	0	≤0.1
14	0	≤0.1
16	0	8.6–16.5
16	1	≤0.5
18	0	1.0–3.3
18	1	20.0–42.2
18	2	39.4–62.0
18	3	0.5–1.5

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
20	0	≤0.8
20	1	≤0.5
22	0	≤0.3
22	1	≤0.1
24	0	≤0.4

- **FATS AND FIXED OILS** (401), *Procedures, Peroxide Value*: NMT 10.0
- **FATS AND FIXED OILS** (401), *Procedures, Sterol Composition*: The sterol fraction of the Corn Oil contains NMT 0.3% of brassicasterol.
- **FATS AND FIXED OILS** (401), *Procedures, Unsaponifiable Matter*: NMT 1.5%
- **WATER DETERMINATION** (921), *Method I*: NMT 0.1%. Use a mixture of equal volumes of decanol and anhydrous methanol as the solvent.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.
- **LABELING**: Where Corn Oil is intended for use in the manufacture of injectable dosage forms, it is so labeled.
- **OTHER REQUIREMENTS**: For Corn Oil intended for use in injectable dosage forms, specified in *Labeling*, the requirements for *Acid Value*, *Peroxide Value*, *Unsaponifiable Matter*, and *Water* 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
CORN OIL	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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