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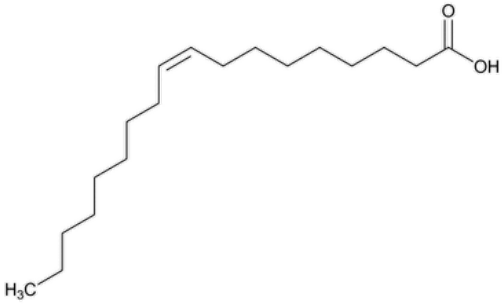
Oleic Acid



$C_{18}H_{34}O_2$ 282.46

9-Octadecenoic acid, (*Z*)-;

Oleic acid CAS RN®: 112-80-1.

DEFINITION

Oleic Acid is manufactured from fats and oils derived from edible sources, animal or vegetable, and consists chiefly of (*Z*)-9-octadecenoic acid [$CH_3(CH_2)_7CH{:}CH(CH_2)_7COOH$]. It contains NLT 65.0% of (*Z*)-9-octadecenoic acid [$CH_3(CH_2)_7CH{:}CH(CH_2)_7COOH$]. It may contain suitable stabilizers.

[NOTE—Oleic Acid labeled solely for external use is exempt from the requirement that it be prepared from edible sources.]

IDENTIFICATION

Change to read:

• **A.** ▲**SPECTROSCOPIC IDENTIFICATION TESTS ⟨197⟩, *Infrared Spectroscopy*: 197F**▲ (CN 1-MAY-2020)

Sample: Undried specimen

Acceptance criteria: Meets the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **PROCEDURE**

Standard solution: 1.7 mg/mL of USP Oleic Acid RS in tetrahydrofuran

Sample solution: 1.7 mg/mL of Oleic Acid in tetrahydrofuran

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary; 0.25-µm layer of phase G25 (or G35)

Temperature

Detector: 280°

Injection port: 280°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
120	—	120	5
120	10	250	20

Carrier gas: Helium

Flow rate: 7.0 mL/min

Injection volume: 1.0 µL

Injection type: Splitless

System suitability

Sample: *Standard solution*

[NOTE—The retention time for oleic acid is about 19.2 min.]

System suitability requirements

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oleic acid in the portion of the sample taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response for oleic acid from the *Sample solution*

r_S = peak response for oleic acid from the *Standard solution*

C_S = concentration of USP Oleic Acid RS in the *Standard solution* (mg/mL)

C_U = concentration of Oleic Acid in the *Sample solution* (mg/mL)

Acceptance criteria: NLT 65.0%

IMPURITIES

• **RESIDUE ON IGNITION ⟨281⟩**

Sample: 10 mL

Acceptance criteria: NMT 1 mg (about 0.01%)

SPECIFIC TESTS

• **CONTENT OF FATTY ACIDS**

Oleic Acid exhibits the composition profiles of fatty acids shown in *Table 2* below, as determined in *Fats and Fixed Oils ⟨401⟩, Fatty Acid Composition*.

Table 2

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
14	0	≤5.0
16	0	≤16.0
16	1	≤8.0
18	0	≤6.0
18	1	≥65.0

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
18	2	≤18.0
18	3	≤4.0
20, 22[a]	0	≤4.0

[a] The sum of these fatty acids should be NMT 4.0%.

Test solution: Prepare as directed in the chapter, but omitting the initial hydrolysis.

- **Congealing Temperature ⟨651⟩:** 3°–10° for Oleic Acid derived from animal sources; 10°–16° for Oleic Acid derived from vegetable sources
- **Fats and Fixed Oils,** *Acid Value* **⟨401⟩:** 196–204, 2 g being used
- **Fats and Fixed Oils,** *Iodine Value* **⟨401⟩:** 85–105
- **Fats and Fixed Oils,** *Peroxide Value* **⟨401⟩:** NMT 10.0
- **Water Determination,** *Method I* **⟨921⟩:** NMT 0.4%
- **Mineral Acids**

  Sample: 5 mL

  Analysis: Shake the *Sample* with an equal volume of water at a temperature of about 25° for 2 min, allow the liquids to separate, and pass the water layer through a paper filter previously moistened with water.

  Acceptance criteria: The filtrate is not reddened by the addition of 1 drop of methyl orange TS.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, protected from light. Store at room temperature, and avoid exposure to excessive heat.
- **Labeling:** If it is for external use only, the labeling so indicates. Label it to indicate whether it is derived from animal or vegetable sources. Indicate the names and quantity of any added stabilizers.
- **USP Reference Standards ⟨11⟩**

  USP Oleic Acid RS

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

Topic/Question	Contact	Expert Committee
OLEIC ACID	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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