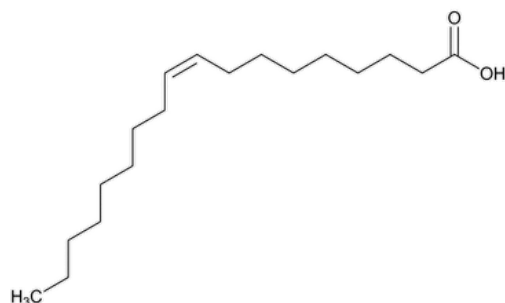


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: NF Monographs
DocId: GUID-0D25CCF6-9210-4BC9-8C95-EF7B11C4849F_2_en-US
DOI: https://doi.org/10.31003/USPNF_M58500_02_01
DOI Ref: u26m6

© 2025 USPC
Do not distribute

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	≥60.0