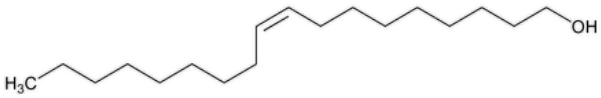
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2015
Document Type: NF Monographs
DocId: GUID-E1D63D36-F2B3-485D-81AA-2FE1E824FAAA_1_en-US
DOI: https://doi.org/10.31003/USPNF_M58590_01_01
DOI Ref: yhr69

Oleyl Alcohol



$C_{18}H_{36}O$ 268.48
9-Octadecen-1-ol, (*Z*)-;
(*Z*)-9-Octadecen-1-ol CAS RN®: 143-28-2.

DEFINITION

Oleyl Alcohol is a mixture of unsaturated and saturated high molecular weight fatty alcohols consisting of 75.0%–102.0% of oleyl alcohol ($C_{18}H_{36}O$) and its isomers. It is obtained from sources of vegetable, animal, or synthetic origin. It may contain suitable stabilizers.

IDENTIFICATION

• **A. Chromatographic Identity**

Analysis: Proceed as directed in the *Assay*.

Acceptance criteria: The retention time of the major peak of the *Sample solution*, excluding the solvent and internal standard peaks, corresponds to the oleyl alcohol peak of the *System suitability solution*.

ASSAY

• **Procedure**

Internal standard solution: 1 mg/mL of 1-pentadecanol (internal standard) in ethanol

System suitability solution: Prepare 1 mg/mL each of USP Cetyl Alcohol RS, USP Stearyl Alcohol RS, and USP Oleyl Alcohol RS in *Internal standard solution*, and heat the solution in a sealed container in a 50° water bath until all fatty alcohols are dissolved. Allow the solution to cool to room temperature, and mix well.

Standard solution: 1.0 mg/mL of USP Oleyl Alcohol RS in *Internal standard solution*

Sample solution: 1.0 mg/mL of Oleyl Alcohol in *Internal standard solution*

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m fused silica capillary; coated with a 0.25-µm layer of phase G7

Temperatures

Detector: 280°

Injection port: 270°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	20	180	—
180	10	220	5

Carrier gas: Hydrogen

Flow rate: 2.0 mL/min, constant flow mode

Injection volume: 1 µL

Injection type: Split injection; split ratio is 100:1

Liner: Single taper, low pressure drop liner with deactivated wool

Run time: 15 min

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See *Table 2* for the relative retention times.]

Table 2

Component	Relative Retention Time
1-Pentadecanol (internal standard)	1.00
Cetyl alcohol	1.08
Stearyl alcohol	1.25
Oleyl alcohol	1.27

Suitability requirements

Resolution: NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl and oleyl alcohol peaks, *System suitability solution*

Tailing factor: 0.8–1.8 for the oleyl alcohol and 1-pentadecanol peaks, *Standard solution*

Relative standard deviation: NMT 1%, using the area ratio of oleyl alcohol to 1-pentadecanol, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

The peak of elaidyl alcohol, which is an isomer of oleyl alcohol, can be resolved from the oleyl alcohol peak with a resolution of about 1, and with a relative retention time with reference to oleyl alcohol of 0.995. An additional small peak that may be observed on the peak tail of oleyl alcohol can be assigned to another oleyl alcohol isomer. If elaidyl alcohol is observed, a combination of both peaks of elaidyl alcohol and oleyl alcohol is used to determine oleyl alcohol content.

Calculate the percentage of oleyl alcohol ($C_{18}H_{36}O$) or its isomers in the portion of Oleyl Alcohol taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of oleyl alcohol (or elaidyl alcohol) to the internal standard [peak response of oleyl alcohol (or elaidyl alcohol)/peak response of the internal standard] from the *Sample solution*

R_S = peak response ratio of oleyl alcohol to the internal standard (peak response of oleyl alcohol/peak response of the internal standard) from the *Standard solution*

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

C_U = concentration of Oleyl Alcohol in the *Sample solution* (mg/mL)

Acceptance criteria: 75.0%–102.0% for oleyl alcohol and its isomers

IMPURITIES

• **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%, determined on 2 g

• **LIMIT OF RELATED FATTY ALCOHOLS**

Resolution solution: Prepare 1 mg/mL each of USP Cetyl Alcohol RS, USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, USP Linoleyl Alcohol RS, USP Linolenyl Alcohol RS, and USP Arachidyl Alcohol RS in ethanol. Heat the solution in a sealed container in a 50° water bath until all fatty alcohols are dissolved. Allow the solution to cool to room temperature, and mix well. Dilute the solution with ethanol to obtain a solution

containing 0.05 mg/mL each of USP Cetyl Alcohol RS, USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, USP Linoleyl Alcohol RS, USP Linolenyl Alcohol RS, and USP Arachidyl Alcohol RS.

Sample solution: 1 mg/mL of Oleyl Alcohol in ethanol

Chromatographic system: Proceed as directed in the *Assay*, except use split injection with a split ratio of 5:1.

System suitability

Sample: *Resolution solution*

[NOTE—See *Table 3* for the relative retention times.]

Table 3

Component	Relative Retention Time
Cetyl alcohol	0.85
Stearyl alcohol	0.99
Oleyl alcohol	1.00
Linoleyl alcohol	1.03
Linolenyl alcohol	1.06
Arachidyl alcohol	1.14

Suitability requirements

Resolution: NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl and oleyl alcohol peaks; NLT 6.0 between the oleyl alcohol and linoleyl alcohol peaks

Analysis

Samples: *Resolution solution* and *Sample solution*

Identify each related fatty alcohol peak in the *Sample solution* based on that in the *Resolution solution*.

Calculate the percentage of each related fatty alcohol in the portion of Oleyl Alcohol taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each related fatty alcohol from the *Sample solution*

r_T = sum of all the peak responses excluding peak responses due to solvent from the *Sample solution*

Acceptance criteria: See *Table 4*. Disregard peaks that are less than 0.05% for any unspecified impurities, and any peaks due to solvent.

Table 4

Component	Acceptance Criteria, NMT (%)
Cetyl alcohol	8.0
Stearyl alcohol	5.0
Linoleyl alcohol	7.0
Linolenyl alcohol	1.0
Arachidyl alcohol	1.0

SPECIFIC TESTS

- **Fats and Fixed Oils,** *Acid Value* ⟨401⟩**:** NMT 1
- **Fats and Fixed Oils,** *Hydroxyl Value* ⟨401⟩**:** 205–215
- **Fats and Fixed Oils,** *Peroxide Value* ⟨401⟩**:** NMT 10.0
- **Water Determination,** *Method I* ⟨921⟩**:** NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-filled, tight containers, and store at controlled room temperature.
- **Labeling:** Label it to indicate whether it is derived from vegetable, animal, or synthetic sources. Indicate the names and amounts of any added stabilizers.
- **USP Reference Standards** ⟨11⟩
  USP Arachidyl Alcohol RS
  USP Cetyl Alcohol RS
  USP Linolenyl Alcohol RS
  USP Linoleyl Alcohol RS
  USP Oleyl Alcohol RS
  USP Stearyl Alcohol RS

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

Topic/Question	Contact	Expert Committee
OLEYL ALCOHOL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(2)

Current DocID: GUID-E1D63D36-F2B3-485D-81AA-2FE1E824FAAA_1_en-US
DOI: https://doi.org/10.31003/USPNF_M58590_01_01
DOI ref: yhr69