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Myristyl Alcohol



$C_{14}H_{30}O$ 214.39
n-Tetradecan-1-ol;
1-Tetradecanol;
1-Hydroxytetradecane;
1-Tetradecyl alcohol CAS RN®: 112-72-1.

DEFINITION
Myristyl Alcohol contains NLT 90.0% and NMT 102.0% of myristyl alcohol ($C_{14}H_{30}O$), the remainder consisting chiefly of related alcohols. It is obtained from sources of vegetable, animal, or synthetic origin.

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 myristyl alcohol peak of the *Standard solution*.

ASSAY

- PROCEDURE**
Internal standard solution: 1 mg/mL of 1-pentadecanol (internal standard) in ethanol
System suitability solution: Prepare 1 mg/mL of [USP Cetyl Alcohol RS](#), 1 mg/mL of [USP Stearyl Alcohol RS](#), and 1 mg/mL of [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 Myristyl Alcohol RS](#) in *Internal standard solution*
Sample solution: 1.0 mg/mL of Myristyl 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 column, coated with a 0.25-µm layer of phase G7
Temperatures
Injection port: 270°
Detector: 280°
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
Myristyl alcohol	0.92
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 alcohol and oleyl alcohol peaks, *System suitability solution*

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of myristyl alcohol ($C_{14}H_{30}O$) in the portion of Myristyl Alcohol taken:

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

R_U = peak response ratio of myristyl alcohol to the internal standard (peak response of myristyl alcohol/peak response of the internal standard) from the *Sample solution*

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

C_S = concentration of [USP Myristyl Alcohol RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–102.0%

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%, determined on 2 g

• **LIMIT OF RELATED FATTY ALCOHOLS**

Solution A: 1 mg/mL of 1-pentadecanol in ethanol

Resolution solution: Prepare 1 mg/mL of [USP Lauryl Alcohol RS](#), 1 mg/mL of [USP Myristyl Alcohol RS](#), 1 mg/mL of [USP Cetyl Alcohol RS](#), 1 mg/mL of [USP Stearyl Alcohol RS](#), and 1 mg/mL of [USP Oleyl Alcohol RS](#) in *Solution A*. 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 Lauryl Alcohol RS](#), [USP Myristyl Alcohol RS](#), [USP Cetyl Alcohol RS](#), 1-pentadecanol, [USP Stearyl Alcohol RS](#), and [USP Oleyl Alcohol RS](#).

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

Chromatographic system: Proceed as directed in the Assay, except for the split ratio.

Injection type: Split injection; split ratio is 5:1

System suitability

Sample: Resolution solution

[NOTE—See [Table 3](#) for the relative retention times.]

Table 3

Component	Relative Retention Time
Lauryl alcohol	0.79
Myristyl alcohol	0.92
1-Pentadecanol	1.00
Cetyl alcohol	1.08
Stearyl alcohol	1.25
Oleyl alcohol	1.27

Suitability requirements

Resolution: NLT 15 between myristyl alcohol and 1-pentadecanol peaks; NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl alcohol and oleyl 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 or any unspecified impurity in the portion of Myristyl Alcohol taken:

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

r_U = peak response of each related fatty alcohol (or any unspecified impurity) from the *Sample solution*

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

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

Sum of unspecified impurities: NMT 1%

Sum of related fatty alcohols and unspecified impurities: NMT 10.0%

SPECIFIC TESTS

- **FATS AND FIXED OILS, Acid Value (401):** NMT 2
- **FATS AND FIXED OILS, Iodine Value (401):** NMT 1
- **FATS AND FIXED OILS, Hydroxyl Value (401):** 250–267
- **WATER DETERMINATION, Method I (921):** NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label it to indicate whether it is derived from vegetable, animal, or synthetic sources.
- **USP REFERENCE STANDARDS (11).**
 - USP Cetyl Alcohol RS
 - USP Lauryl Alcohol RS
 - USP Myristyl 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
MYRISTYL ALCOHOL	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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