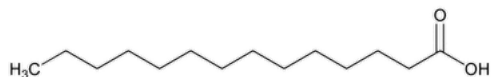


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Myristic Acid



$C_{14}H_{28}O_2$ 228.37

Tetradecanoic acid;

1-Tetradecanoic acid;

1-Tridecanecarboxylic acid CAS RN®: 544-63-8.

DEFINITION

Myristic Acid is obtained from coconut oil and other fats. It contains NLT 97.0% of myristic acid ($C_{14}H_{28}O_2$).

IDENTIFICATION

Change to read:

- **A.** **▲** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: \(197D\)](#) **▲** (CN 1-MAY-2020) or [\(197K\)](#).

Sample: Undried specimen

Acceptance criteria: Meets the requirements

Change to read:

- **B.** **▲** **CHROMATOGRAPHIC IDENTITY:** **▲** (2S (NF36)) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained **▲** **▲** (2S (NF36)) in the Assay.

ASSAY

Delete the following:

- ▲ [FATS AND FIXED OILS, Fatty Acid Composition \(401\)](#).

System suitability solution: Prepare as directed in the chapter, except that only stearic acid and palmitic acid are used.

Sample solution: Prepare as directed for the *Test Solution* in the chapter.

Standard solution: Prepare as directed for the *Sample solution*, using 100 mg of [USP Myristic Acid RS](#) instead of the substance to be examined.

Chromatographic system: Prepare as directed in the chapter.

Injection size: 1 μ L

System suitability

(See [Chromatography \(621\)](#), [System Suitability](#).)

Sample: System suitability solution

Suitability requirements

Resolution: NLT 1.5 between methyl stearate and methyl palmitate

Analysis

Samples: *Standard solution* and *Sample solution*

Identify the methyl myristate peak from the *Sample solution* by comparing the retention times of the peaks with those from the *Standard solution*. Measure the responses for all the peaks from the *Sample solution*, excluding the solvent peak.

Calculate the percentage of myristic acid ($C_{14}H_{28}O_2$) in the portion of Myristic Acid taken:

$$\text{Result} = (A/B) \times 100$$

A = peak response for methyl myristate from the *Sample solution*

B = sum of all the peak responses in the *Sample solution* except the solvent peak

Acceptance criteria: NLT 97.0% **▲** (2S (NF36))

Add the following:

- ▲ **Procedure**

Solution A: Add 1 mL of [phosphoric acid](#) to 1 L of water to prepare a 0.1% phosphoric acid solution.

Solution B: Acetonitrile

Diluent: [Methanol](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	50	50
20.0	1	99
25.0	1	99
26.0	50	50
30.0	50	50

System suitability solution: 5.0 mg/mL of [USP Myristic Acid RS](#) and 0.025 mg/mL of linolenic acid in *Diluent*

Standard solution: 5.0 mg/mL of [USP Myristic Acid RS](#) in *Diluent*

Sample solution: 5.0 mg/mL of Myristic Acid in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 2.7-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 25 μL

Run time: 30 min

System suitability

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

[NOTE—The relative retention times for linolenic acid and myristic acid are 0.97 and 1.00, respectively.]

Suitability requirements

Resolution: NLT 1.5 between linolenic acid and myristic acid, *System suitability solution*

Tailing factor: 0.8–1.8, *Standard solution*

Relative standard deviation: NMT 0.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of myristic acid ($C_{14}H_{28}O_2$) in the portion of Myristic Acid taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: NLT 97.0%▲ (2S (NF36))

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Add the following:

▲ Limit of Lauric Acid and Palmitic Acid

Solution A, Solution B, Diluent, Mobile phase, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.15 mg/mL of [USP Lauric Acid RS](#) and 0.15 mg/mL of [USP Palmitic Acid RS](#) in *Diluent*

Sample solution: 5.0 mg/mL of Myristic Acid in *Diluent*

System suitability