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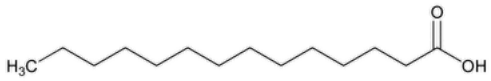
Myristic Acid



$C_{14}H_{28}O_2$ 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 µL

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

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

[NOTE—The relative retention times for lauric acid, linolenic acid, myristic acid, and palmitic acid are 0.73, 0.97, 1.00, and 1.26, respectively.]

Suitability requirements

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

Relative standard deviation: NMT 5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Based on the *Standard solution*, identify the peaks of appropriate fatty acids.

Calculate the percentage of lauric acid ($C_{12}H_{24}O_2$) or palmitic acid ($C_{16}H_{32}O_2$) in the portion of Myristic Acid taken:

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

r_U = peak response of lauric acid or palmitic acid from the *Sample solution*

r_S = peak response of lauric acid or palmitic acid from the *Standard solution*

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

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

Acceptance criteria: Disregard peaks that are less than 0.05% for any individual impurity and any peaks due to solvent.

Sum of lauric acid and palmitic acid: NMT 3.0%▲ (2S (NF36))

• **LIMIT OF LEAD**

[NOTE—Select reagents with as low a lead content as practicable, and store all solutions in high-density polyethylene containers. Rinse all plastic and glassware thoroughly with warm 8 N nitric acid followed by deionized water.]

Standard stock solution: Dissolve 160 mg of lead nitrate in 100 mL of water containing 1 mL of nitric acid. Dilute with water to 1000 mL.

Standard solutions: [NOTE—Prepare these solutions on the day of use.] Transfer 10.0 mL of *Standard stock solution* to a 100-mL volumetric flask, and dilute with water to volume. Each milliliter of this solution contains the equivalent of about 10 µg of lead. Dilute accurately measured volumes of the diluted *Standard stock solution* with water to obtain solutions with known concentrations of 1, 2, and 5 µg/mL of lead.

Sample solution: Transfer 5 g of Myristic Acid to an evaporating dish. Add 5 mL of a 25% sulfuric acid solution, and distribute the sulfuric acid uniformly through the sample. Within a hood, place the dish on a steam bath to evaporate most of the water. Place the dish on a burner, and slowly pre-ash the sample by expelling most of the sulfuric acid. Place the dish in a muffle furnace that has been set at 525°, and ash the sample until the residue appears free from carbon. Prepare a blank by ashing 5 mL of a 25% sulfuric acid solution. Cool, and cautiously wash down the inside of each evaporation dish with water. Treat both the sample and the blank as follows. Add 5 mL of 1 N hydrochloric acid. Place each dish on a steam bath, and evaporate to dryness. To each dish add 1.0 mL of 3 N hydrochloric acid and about 5 mL of water, and heat briefly on a steam bath to dissolve any residue. Transfer each solution quantitatively to a 10-mL volumetric flask, and dilute with water to volume.

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 283.3 nm at the lead emission line

Lamp: Lead electrodeless discharge

Flame: Air–acetylene with a suitable burner head

Slit width: 0.7 nm

Blank: Water. [NOTE—Perform a blank determination following the manufacturer's operating instructions.]

Analysis

Samples: *Standard solutions*, *Sample solution*, and *Blank*

Determine the corrected absorbance values by subtracting the absorbance of the *Blank* from the absorbance of each of the *Standard solutions* and from the absorbance of the *Sample solution*. Prepare a standard curve by plotting the corrected absorbance values of the *Standard solutions* versus their corresponding concentrations, in µg/mL. From the calibration curve, determine the lead concentration in the *Sample solution*.

Calculate the lead content, in ppm, in the portion of Myristic Acid taken:

$$\text{Result} = (C/W_S) \times V$$

C = measured concentration of lead in the *Sample solution* from the standard curve (µg/mL)

W_S = weight of Myristic Acid taken (g)

V = final volume of the *Sample solution*, 10 mL

Acceptance criteria: NMT 2 ppm

• **Limit of Mineral Acids**

Sample: 5 g of melted Myristic Acid

Analysis: Shake the *Sample* with an equal volume of hot water for 2 min, cool, and filter.

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

SPECIFIC TESTS

• **Congealing Temperature** ⟨651⟩**:** 48°–55.5°

• **Fats and Fixed Oils** ⟨401⟩, *Procedures, Acid Value***:** 242–249

• **Fats and Fixed Oils** ⟨401⟩, *Procedures, Iodine Value***:** NMT 1.0

• **Fats and Fixed Oils** ⟨401⟩, *Procedures, Peroxide Value***:** NMT 10.0

• **Fats and Fixed Oils** ⟨401⟩, *Procedures, Unsaponifiable Matter***:** NMT 1%

• **Water Determination** ⟨921⟩, *Method I***:** NMT 0.2%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. No storage requirements specified.

Change to read:

• **USP Reference Standards** ⟨11⟩

▲USP Lauric Acid RS▲ (2S (NF36))

USP Myristic Acid RS

▲USP Palmitic Acid RS▲ (2S (NF36))

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

Topic/Question	Contact	Expert Committee
MYRISTIC ACID	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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