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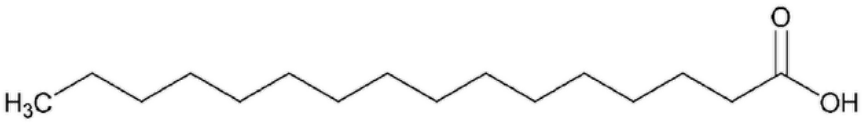
Palmitic Acid



$C_{16}H_{32}O_2$ 256.42

n-Hexadecanoic acid;

1-Pentadecanecarboxylic acid CAS RN®: 57-10-3.

DEFINITION

Change to read:

Palmitic Acid is a mixture of ▲fatty▲ (2S (NF36)) acids obtained from fats or oils of animal or vegetable origin. It contains NLT 92.0% of palmitic acid ($C_{16}H_{32}O_2$) and NMT 6.0% of stearic acid ($C_{18}H_{36}O_2$).

IDENTIFICATION

Change to read:

• **A. ▲Chromatographic Identity:▲** (2S (NF36)) The retention time of the major peak for palmitic acid of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Add the following:

▲• **B. Acid Value**

Sample: 1 g of Palmitic Acid

Analysis: Proceed as directed in *Fats and Fixed Oils ⟨401⟩, Procedures, Acid Value*.

Acceptance criteria: 216–220▲ (2S (NF36))

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** Add 1 mL of phosphoric acid to 1 L of water. This is 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

Time (min)	Solution A (%)	Solution B (%)
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 Palmitic Acid RS in *Diluent*

Sample solution: 5.0 mg/mL of Palmitic 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, myristic acid, and palmitic acid are 0.77, 0.80, and 1.00, respectively.]

Suitability requirements

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

Tailing factor: 0.8–1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of palmitic acid ($C_{16}H_{32}O_2$) in the portion of Palmitic 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 Palmitic Acid RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: NLT 92.0% of palmitic acid ($C_{16}H_{32}O_2$)▲ (2S (NF36))

IMPURITIES

Delete the following:

▲• **HEAVY METALS,** *Method II ⟨231⟩*: NMT 10 ppm ▲ (Official 1-Jan-2018)

Add the following:

▲• **Limit of Stearic Acid, Myristic Acid, and Other Related Fatty Acids**

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

Standard solution: 0.3 mg/mL of USP Stearic Acid RS, 0.1 mg/mL of USP Myristic Acid RS, and 0.05 mg/mL of USP Palmitic Acid RS in *Diluent*

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

System suitability

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

[NOTE—The relative retention times for linolenic acid, myristic acid, palmitic acid, and stearic acid are 0.77, 0.80, 1.00, and 1.17, 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* and Table 2, identify the peaks of appropriate fatty acids.

[NOTE—The relative retention times for several fatty acids are provided in Table 2.]

Table 2

Fatty Acid	Relative Retention Time	Relative Response Factor
Caprylic acid	0.20	1.85
Capric acid	0.36	1.54
Lauric acid	0.57	1.34
Myristic acid	0.80	—
Palmitic acid	1.00	1.00
Stearic acid	1.17	—

Calculate the percentage of myristic acid ($C_{14}H_{28}O$) or stearic acid ($C_{18}H_{36}O_2$) in the portion of Palmitic Acid taken:

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

r_U = peak response of myristic acid or stearic acid from the *Sample solution*

r_S = peak response of myristic acid or stearic acid from the *Standard solution*

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

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

Calculate the percentage of any other single fatty acid (caprylic acid, capric acid, or lauric acid, if present) in the portion of Palmitic Acid taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of any other single fatty acid (caprylic acid, capric acid, or lauric acid, if present) from the *Sample solution*

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

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

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

F = relative response factor for any other single fatty acid (caprylic acid, capric acid, or lauric acid, if present) (see Table 2)

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

Stearic acid: NMT 6.0%

Myristic acid: NMT 2.0%

Any other single fatty acid (caprylic acid, capric acid, or lauric acid): NMT 1.0%▲ (2S (NF36))

SPECIFIC TESTS

• **COLOR:** Heat a sample of Palmitic Acid to 75°. The resulting liquid is not more intensely colored than a solution prepared by mixing 1.2 mL of ferric chloride CS and 0.3 mL of cobaltous chloride CS with 0.3 N hydrochloric acid to make 10 mL, and diluting 5 mL of this solution with 0.3 N hydrochloric acid to make 100 mL. Make the comparison by viewing the solutions downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* ⟨631⟩).

• **CONGEALING TEMPERATURE** ⟨651⟩**:** 60°–66°

Delete the following:

▲• **Fats and Fixed Oils,** *Acid Value* ⟨401⟩**:** 216–220, using 1 g▲ (2S (NF36))

• **Fats and Fixed Oils** ⟨401⟩**,** *Procedures, Iodine Value, Method I*

Analysis: Proceed as directed in the chapter, except use 35 mL of chloroform.

Acceptance criteria: NMT 1

• **Mineral Acid**

Analysis: Shake 5 g of melted Palmitic Acid 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.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at room temperature.

• **Labeling:** Label it to indicate whether it is derived from animal or vegetable sources.

Change to read:

• **USP Reference Standards** ⟨11⟩

▲USP Myristic Acid RS▲ (2S (NF36))
USP Palmitic Acid RS
USP Stearic Acid RS

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

Topic/Question	Contact	Expert Committee
PALMITIC ACID	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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