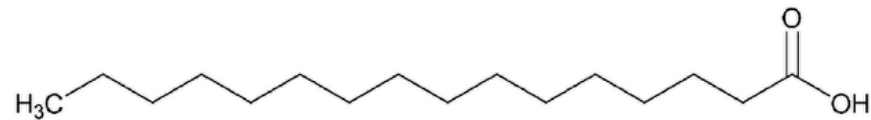


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Palmitic Acid



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