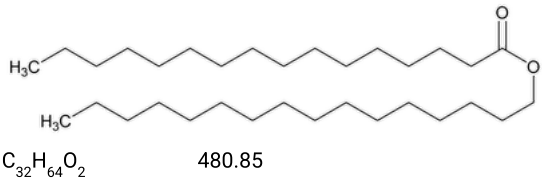


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Cetyl Palmitate

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Hexadecanoic acid hexadecyl ester;
Cetyl palmitate CAS RN®: 540-10-3.

DEFINITION

Cetyl Palmitate contains NLT 90.0% and NMT 103.0% of cetyl palmitate ($C_{32}H_{64}O_2$). It consists of esters of cetyl alcohol and saturated high molecular weight fatty acids, principally palmitic acid.

IDENTIFICATION

- A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197F
Sample: Use a thin film of melted test specimen.
Acceptance criteria: Meets the requirements
- B. CHROMATOGRAPHIC IDENTITY**
Analysis: Proceed as directed in the Assay.
Acceptance criteria: The retention time of the cetyl palmitate peak from the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- PROCEDURE**
Diluent: [n-Hexane](#)
System suitability solution: 1 mg/mL of [USP Cetyl Esters Wax RS](#) in *Diluent*
Standard solution: 1 mg/mL of [USP Cetyl Palmitate RS](#) in *Diluent*
Sample solution: 1 mg/mL of Cetyl Palmitate in *Diluent*
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: GC
Detector: Flame ionization
Column: 0.53-mm × 10-m fused-silica capillary; 2.65-μm layer of phase [G2](#)
Temperatures
Injector: 350°
Detector: 350°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	20	300	15

Carrier gas: Helium
Flow rate: 6.5 mL/min

Injection volume: 1 µL

Injection type: Split, split ratio 10:1

Run time: 25 min

System suitability

Sample: System suitability solution

[NOTE—For relative retention times, see [Table 2](#).]

Table 2

Component	Relative Retention Times
Fatty esters with carbon-chain length of carbon number 28	0.79
Fatty esters with carbon-chain length of carbon number 30	0.87
Fatty esters with carbon-chain length of carbon number 32 that consists chiefly of Cetyl Palmitate	1.00
Fatty esters with carbon-chain length of carbon number 34	1.18

Suitability requirements

Resolution: NLT 2.0 between fatty esters with carbon-chain length of carbon number 32 and fatty esters with carbon-chain length of carbon number 34, System suitability solution

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of cetyl palmitate (fatty esters with carbon-chain length carbon number 32) in the portion of Cetyl Palmitate taken:

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

r_U = peak response of cetyl palmitate from the Sample solution

r_S = peak response of cetyl palmitate from the Standard solution

C_S = concentration of [USP Cetyl Palmitate RS](#) in the Standard solution (mg/mL)

C_U = concentration of Cetyl Palmitate in the Sample solution (mg/mL)

Acceptance criteria: 90.0%–103.0%

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.05%

Change to read:

- LIMIT OF FATTY ALCOHOLS, FATTY ACIDS, AND FATTY ESTERS

System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

System suitability

Sample: System suitability solution

[NOTE—For relative retention times, see [Table 3](#).]

Table 3

Component	Relative Retention Times
Cetyl alcohol	0.46
Palmitic acid	0.49
Fatty esters with carbon-chain length of carbon number 28	0.79
Fatty esters with carbon-chain length of carbon number 30	0.87