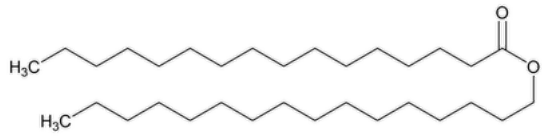


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Cetyl Palmitate

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$C_{32}H_{64}O_2$ 480.85
 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

Component	Relative Retention Times
Fatty esters with carbon-chain length of carbon number 32 that consist 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: *System suitability solution* and *Sample solution*

Identify cetyl alcohol, palmitic acid, and each of the fatty esters in the *Sample solution* based on those in the *System suitability solution* ([Table 3](#)).

Calculate the percentage of cetyl alcohol, palmitic acid, and each of the fatty esters in the portion of Cetyl Palmitate taken:

Result = $(r_U/r_T) \times 100$

r_U = peak area of cetyl alcohol, palmitic acid, and each of the fatty esters from the *Sample solution*

r_T = sum of the total peak areas from the *Sample solution*, except for the peak areas from solvent

Acceptance criteria: See [Table 4](#).

Table 4

Component	Acceptance Criteria, NMT (%)
Cetyl alcohol	2.6
Palmitic acid	0.65
Fatty esters with carbon-chain length of carbon number 28	▲0.5▲ (RB 1-Jul-2024)
Fatty esters with carbon-chain length of carbon number 30	▲2.0▲ (RB 1-Jul-2024)
Fatty esters with carbon-chain length of carbon number 34	1.5
Any individual unidentified impurity	0.25
Sum of fatty alcohols, fatty acids, fatty esters with carbon-chain length of carbon number 28, 30, and 34, and unidentified impurities	10.0

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#), [Procedures, Procedure for Class II](#): 46°–53°
- [FATS AND FIXED OILS \(401\)](#), [Procedures, Acid Value](#): NMT 1
- [FATS AND FIXED OILS \(401\)](#), [Procedures, Hydroxyl Value](#): NMT 6
- [FATS AND FIXED OILS \(401\)](#), [Procedures, Iodine Value](#): NMT 1
- [FATS AND FIXED OILS \(401\)](#), [Procedures, Saponification Value](#): 110–130
- [LOSS ON DRYING \(731\)](#)
Analysis: Dry at 105° for 1 h.
Acceptance criteria: NMT 3.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers at controlled room temperature, and avoid exposure to excessive heat.
- [USP REFERENCE STANDARDS \(11\)](#).

[USP Cetyl Palmitate RS](#)
[USP Cetyl Esters Wax RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CETYL PALMITATE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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