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Cetyl Esters Wax

DEFINITION

Cetyl Esters Wax is a mixture consisting primarily of esters of saturated fatty alcohols (C_{12} to C_{18}) and saturated fatty acids (C_{12} to C_{20}). It contains NLT 90.0% of total saturated fatty esters and NLT 10.0% of fatty esters with carbon-chain length of carbon number 32 that consist chiefly of cetyl palmitate.

IDENTIFICATION

• **A. CHROMATOGRAPHIC IDENTITY**

Analysis: Proceed as directed in the test for *Total Fatty Esters and Cetyl Palmitate* in the Assay.

Acceptance criteria: The retention times of the four major fatty ester peaks (fatty esters with carbon-chain length of carbon number 28, fatty esters with carbon-chain length of carbon number 30, fatty esters with carbon-chain length of carbon number 32, and fatty esters with carbon-chain length of carbon number 34) of the *Sample solution* correspond to those of *Reference solution D*.

• **B. [FATS AND FIXED OILS \(401\)](#), [Procedures](#), [Saponification Value](#):** 109–120

ASSAY

• **TOTAL FATTY ESTERS AND CETYL PALMITATE**

Reference solution A: 1 mg/mL of [USP Lauryl Alcohol RS](#), 1 mg/mL of [USP Myristyl Alcohol RS](#), 1 mg/mL of [USP Cetyl Alcohol RS](#), and 1 mg/mL of [USP Stearyl Alcohol RS](#) in [n-hexane](#)

Reference solution B: 1 mg/mL of [USP Palmitic Acid RS](#) in [n-hexane](#)

Reference solution C: 1 mg/mL of [USP Cetyl Palmitate RS](#) in [n-hexane](#)

Reference solution D: 1 mg/mL of [USP Cetyl Esters Wax RS](#) in [n-hexane](#)

Sample solution: 1 mg/mL of Cetyl Esters Wax in [n-hexane](#)

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

Injection port: 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 ratio, 10:1

Run time: 25 min

System suitability

Samples: *Reference solution A*, *Reference solution B*, *Reference solution C*, and *Reference solution D*
[NOTE—For relative retention times, see [Table 2](#).]

Table 2

Component	Relative Retention Times
Lauryl alcohol	0.31
Lauric acid	0.34
Myristyl alcohol	0.39
Myristic acid	0.42
Cetyl alcohol	0.46
Palmitic acid	0.49
Stearyl alcohol	0.53
Stearic acid	0.55
Fatty esters with carbon-chain length of carbon number 26	0.72
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 consist chiefly of cetyl palmitate	1.00
Fatty esters with carbon-chain length of carbon number 34	1.18
Fatty esters with carbon-chain length of carbon number 36	1.44

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, *Reference solution D*

Analysis

Samples: *Reference solution A, Reference solution B, Reference solution C, Reference solution D, and Sample solution*

Identify fatty alcohols, fatty acids, and fatty esters based on the chromatograms from *Reference solution A, Reference solution B, Reference solution C, and Reference solution D*, and also according to [Table 2](#).

Calculate the percentage of each individual group of fatty esters (fatty esters with carbon-chain length of carbon number 26, fatty esters with carbon-chain length of carbon number 28, fatty esters with carbon-chain length of carbon number 30, fatty esters with carbon-chain length of carbon number 32, fatty esters with carbon-chain length of carbon number 34, or fatty esters with carbon-chain length of carbon number 36) (P_{FE}) in the portion of Cetyl Esters Wax taken:

$$\text{Result } (P_{FE}) = (r_U / r_T) \times 100$$

r_U = peak area of each individual group of fatty esters (fatty esters with carbon-chain length of carbon number 26, fatty esters with carbon-chain length of carbon number 28, fatty esters with carbon-chain length of carbon number 30, fatty esters with carbon-chain length of carbon number 32, fatty esters with carbon-chain length of carbon number 34, or fatty esters with carbon-chain length of carbon number 36) from the *Sample solution*

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

Calculate the percentage of total saturated fatty esters in the portion of Cetyl Esters Wax taken:

$$\text{Result} = \Sigma P_{FE}$$

Acceptance criteria

Total saturated fatty esters: NLT 90.0%

Fatty esters with carbon-chain length of carbon number 32 that consist chiefly of cetyl palmitate: NLT 10.0%

IMPURITIES

• **LIMIT OF TOTAL FREE FATTY ALCOHOLS AND FREE FATTY ACIDS**

Reference solution A, Reference solution B, Reference solution D, Sample solution, Chromatographic system, and System

suitability: Proceed as directed in the test for *Total Fatty Esters and Cetyl Palmitate*.

Analysis

Samples: *Reference solution A, Reference solution B, Reference solution D, and Sample solution*