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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*

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

Calculate the percentage of each individual fatty alcohol (lauryl alcohol, myristyl alcohol, cetyl alcohol, or stearyl alcohol) or fatty acid (lauric acid, myristic acid, palmitic acid, or stearic acid) (P_{FA}) in the portion of Cetyl Esters Wax taken:

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

r_U = peak area of each individual fatty alcohol (lauryl alcohol, myristyl alcohol, cetyl alcohol, or stearyl alcohol) or fatty acid (lauric acid, myristic acid, palmitic acid, or stearic acid) 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 fatty alcohols and fatty acids in the portion of Cetyl Esters Wax taken:

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

Acceptance criteria

Total free fatty alcohols and free fatty acids: NMT 10.0%

SPECIFIC TESTS

- **Melting Range or Temperature** ⟨741⟩, *Procedures, Procedure for Class II*: 43°–47°
- **Fats and Fixed Oils** ⟨401⟩, *Procedures, Acid Value*: NMT 5
- **Fats and Fixed Oils** ⟨401⟩, *Procedures, Iodine Value*: NMT 1
- **Paraffin and Free Acids**

  Sample: 1 g

  Analysis: Dissolve the *Sample* in 50 mL of boiling alcohol.

  Acceptance criteria: The *Sample* dissolves completely, and the resulting solution is neutral or acidic to moistened litmus paper.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, in a dry place, and prevent exposure to excessive heat.
- **Labeling:** Label to indicate the percentages of 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, and fatty esters with carbon-chain length of carbon number 36.
- **USP Reference Standards** ⟨11⟩

  USP Cetyl Alcohol RS
  USP Cetyl Esters Wax RS
  USP Cetyl Palmitate RS
  USP Lauryl Alcohol RS
  USP Myristyl Alcohol RS
  USP Palmitic Acid RS
  USP Stearyl Alcohol RS

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

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

Chromatographic Database Information: Chromatographic Database

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