U.S. PHARMACOPEIA

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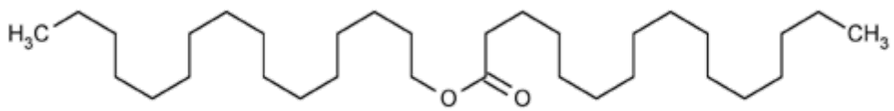
Cetyl Palmitate



$C_{32}H_{64}O_2$ 480.87

Hexadecanoic acid hexadecyl ester.

Cetyl palmitate [*540-10-3*].

» Cetyl Palmitate consists of esters of cetyl alcohol and saturated high molecular weight fatty acids, principally palmitic acid.

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*.

Identification—

A: *Infrared Absorption* ⟨ 197F ⟩ — Use a thin film of melted test specimen.

B: The retention times of the peaks corresponding to cetyl alcohol and palmitic acid in the chromatogram of the *Test solution* correspond to those in the chromatogram of the *System suitability solution*, as obtained in the *Content of palmitic acid* test.

Melting range, *Class II* ⟨ 741 ⟩ : between 46° and 53°.

Acid value ⟨ 401 ⟩ : not more than 1.

Hydroxyl value ⟨ 401 ⟩ : not more than 6.

Iodine value ⟨ 401 ⟩ : not more than 1.

Saponification value ⟨ 401 ⟩ : between 110 and 130.

Loss on drying ⟨ 731 ⟩ **—** Dry it at 105° for 1 hour: it loses not more than 3.0% of its weight.

Residue on ignition ⟨ 281 ⟩ : not more than 0.05%.

Heavy metals, *Method II* ⟨ 231 ⟩ : 0.002%.

Content of palmitic acid—

System suitability solution— Transfer accurately weighed quantities of about 20 mg each of cetyl alcohol, stearic acid, palmitic acid, and oleic acid to a 25-mL conical flask fitted with a suitable water-cooled reflux condenser and a magnetic stir bar, and proceed as directed for *Test Solution* in *Fatty Acid Composition* under *Fats and Fixed Oils* ⟨ 401 ⟩ , beginning with “Add 5.0 mL of a solution prepared by dissolving.”

Test solution— Proceed as directed for *Test Solution* in *Fatty Acid Composition* under *Fats and Fixed Oils* ⟨ 401 ⟩ .

Chromatographic system (see *Chromatography* ⟨ 621 ⟩)— Prepare as directed for *Fatty Acid Composition* under *Fats and Fixed Oils* ⟨ 401 ⟩ . Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.87 for methyl palmitate, 0.96 for cetyl alcohol, 0.99 for methyl stearate, and 1.0 for methyl oleate; the resolution, *R,* between methyl stearate and methyl oleate is not less than 1.5; the relative standard deviation for the palmitate and stearate peaks for replicate injections is not more than 6.0%; and the relative standard deviation for the response ratio of the palmitate peak to that of stearate for replicate injections is not more than 2.0%.

Procedure— Inject about 1 µL of the *Test solution* into the chromatograph, record the chromatogram, identify the methyl palmitate peak in the chromatogram obtained from the *Test solution* by comparing the retention times of the peaks in that chromatogram with those in the chromatogram obtained from the *System suitability solution*, and measure the areas for all of the peaks excluding the solvent peak. Calculate the percentage of palmitic acid in the portion of Cetyl Palmitate taken by the formula:

$$100(A/B),$$

in which *A* is the peak area of methyl palmitate; and *B* is the sum of the areas for all of the peaks, excluding the solvent and cetyl alcohol peaks. The palmitate peak comprises not less than 90% of the total area for all peaks.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
(Official January 1, 2007)

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist
Expert Committee : (EM105) Excipient Monographs 1
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Phone Number : 1-301-816-8262