U.S. PHARMACOPEIA

Search USP29 Go

Palmitic Acid
$C_{16}H_{32}O_2$ 256.43

Hexadecanoic acid [*57-10-3*].

» Palmitic Acid is a mixture of solid organic acids obtained from fats or oils of animal or vegetable origin. It contains not less than 92.0 percent of $C_{16}H_{32}O_2$ and not more than 6.0 percent of stearic acid ($C_{18}H_{36}O_2$).

Packaging and storage— Preserve in well-closed containers, and store at room temperature.

Labeling— Label it to indicate whether it is derived from animal or vegetable sources.

USP Reference standards ⟨ 11 ⟩ **—** *USP Palmitic Acid RS*. *USP Stearic Acid RS*.

Color— Heat it to about 75°. The resulting liquid is not more intensely colored than a solution prepared by mixing 1.2 mL of ferric chloride CS and 0.3 mL of cobaltous chloride CS with 0.3 N hydrochloric acid to make 10 mL, and diluting 5 mL of this solution with 0.3 N hydrochloric acid to make 100 mL. Make the comparison by viewing the solutions downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* ⟨ 631 ⟩).

Identification— The retention time of the major peak for palmitic acid in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Congealing temperature ⟨ 651 ⟩ **:** between 60° and 66°.

Acid value ⟨ 401 ⟩ **:** between 216 and 220, using about 1 g, accurately weighed.

Iodine value ⟨ 401 ⟩ **:** not more than 1. Proceed as directed in *Method I* except to use 35 mL of chloroform.

Mineral acid— Shake 5 g of melted Palmitic Acid with an equal volume of hot water for 2 minutes, cool, and filter: the filtrate is not reddened by the addition of 1 drop of methyl orange TS.

Heavy metals, *Method II* ⟨ 231 ⟩ **:** 0.001%.

Organic volatile impurities, *Method V* ⟨ 467 ⟩ **:** meets the requirements.

Solvent— Use dimethyl sulfoxide.

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

Assay—

Standard preparation— Prepare the *Standard preparation* in the same manner as the *Assay preparation,* using a mixture of 50 mg of *USP Palmitic Acid RS* and 50 mg of *USP Stearic Acid RS* instead of the substance to be examined.

Assay preparation— 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 *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.9 for methyl palmitate and 1.0 for methyl stearate; the resolution, *R,* between methyl stearate and methyl palmitate is not less than 3.0.

Procedure— Separately inject equal volumes (about 1 µL) of the *Assay preparation* and the *Standard preparation* into the chromatograph, record the chromatograms, identify the methyl palmitate peak in the chromatogram obtained from the *Assay preparation* by comparing the retention times of the peaks in that chromatogram with those in the chromatogram obtained from the *Standard preparation,* and measure the responses for all the peaks, excluding the solvent peak. Calculate the percentage of $C_{16}H_{32}O_2$ in the portion of Palmitic Acid taken by the formula:

$$100A/B,$$

in which *A* is the methyl palmitate peak response; and *B* is the sum of the responses of all the peaks in the chromatogram except the solvent peak. Similarly calculate the percentage of stearic acid in the portion of Palmitic Acid taken.

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist
Expert Committee : (EM105) Excipient Monographs 1
USP29–NF24 Page 3385
Pharmacopeial Forum : Volume No. 30(3) Page 987
Phone Number : 1-301-816-8262