U.S. PHARMACOPEIA

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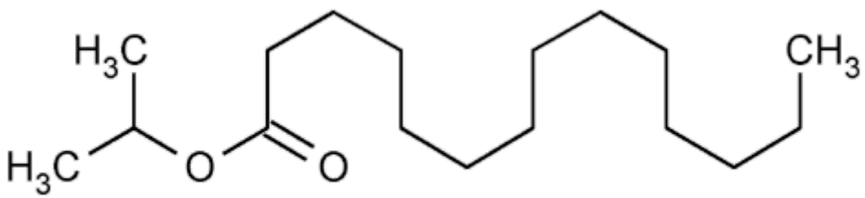
Isopropyl Myristate



$C_{17}H_{34}O_2$ 270.46

Tetradecanoic acid, 1-methylethyl ester.

Isopropyl myristate [*110-27-0*].

» Isopropyl Myristate consists of esters of isopropyl alcohol and saturated high molecular weight fatty acids, principally myristic acid. It contains not less than 90.0 percent of $C_{17}H_{34}O_2$.

Packaging and storage— Preserve in tight, light-resistant containers.

USP Reference standards ⟨ 11 ⟩ **—** *USP Isopropyl Myristate RS*. *USP Isopropyl Palmitate RS*.

Identification— The retention time of the major peaks obtained in the *Assay* is the same as that of the corresponding peaks obtained from the *System suitability solution* employed in the *Assay*.

Specific gravity ⟨ 841 ⟩ : between 0.846 and 0.854.

Acid value ⟨ 401 ⟩ : not more than 1.

Iodine value ⟨ 401 ⟩ : not more than 1.

Saponification value ⟨ 401 ⟩ : between 202 and 212.

Refractive index ⟨ 831 ⟩ : between 1.432 and 1.436 at 20°.

Residue on ignition ⟨ 281 ⟩ : not more than 0.1%.

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

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

Assay—

System suitability solution— Dissolve about 45 mg of *USP Isopropyl Myristate RS* and 5 mg of *USP Isopropyl Palmitate RS* in 10.0 mL of *n*-hexane.

Assay preparation— Dissolve 125 mg of Isopropyl Myristate in 25.0 mL of *n*-hexane, and mix.

Chromatographic system (see *Chromatography* ⟨ 621 ⟩)— The gas chromatograph is equipped with a flame-ionization detector and a 4-mm × 1.8-m column packed with 10% liquid phase G8 on 100- to 120-mesh support S1A. The carrier gas is nitrogen, flowing at a rate of 45 mL per minute. The column temperature is programmed to rise from 90° to 210° at a rate of 2° per minute and then to maintain at 210° for 8 minutes. The detector temperature is maintained at 280°, and the injection port temperature is maintained at 240°. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the relative retention times for isopropyl myristate and isopropyl palmitate are about 1 and 1.3, respectively; the resolution, *R,* is not less than 6.0 between the peaks due to isopropyl myristate and isopropyl palmitate; the tailing factor for the isopropyl palmitate peak is not more than 2; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Inject about 5 µL of the *Assay preparation* into the chromatograph, record the chromatogram, and measure the responses for the major peaks. Calculate the percentage of $C_{17}H_{34}O_2$ in the portion of Isopropyl Myristate taken by the formula:

$$100A/B,$$

in which *A* is the isopropyl myristate peak response; and *B* is the sum of the responses of all the peaks in the chromatogram, except the solvent peak.

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