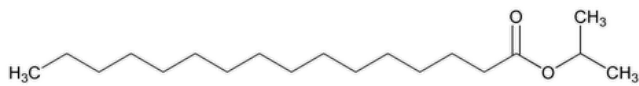


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Isopropyl Palmitate



$C_{19}H_{38}O_2$ 298.50
Hexadecanoic acid, 1-methylethyl ester;
Isopropyl palmitate CAS RN®: 142-91-6.

DEFINITION

Isopropyl Palmitate consists of esters of isopropyl alcohol and saturated high molecular weight fatty acids. It contains NLT 90.0% of isopropyl palmitate ($C_{19}H_{38}O_2$).

IDENTIFICATION

- **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *System suitability solution*, as obtained in the Assay.

ASSAY

PROCEDURE

System suitability solution: 5.0 mg/mL of [USP Isopropyl Palmitate RS](#) and 0.5 mg/mL of [USP Isopropyl Myristate RS](#) in *n*-hexane

Sample solution: 5.0 mg/mL of Isopropyl Palmitate in *n*-hexane

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 15-m fused silica; coated with a 1.0-μm layer of stationary phase G27

Temperatures

Injection port: 240°

Detector: 280°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
150	—	150	1
150	6	230	8

Carrier gas: Helium

Flow rate: 1.5 mL/min

Injection volume: 2.0 μL

Injection type: Split injection, split ratio 10:1

Run time: 22 min

System suitability

Sample: System suitability solution

[NOTE—The relative retention times for isopropyl myristate and isopropyl palmitate are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 6.0 between the isopropyl myristate and isopropyl palmitate peaks

Tailing factor: NMT 2 for the isopropyl palmitate peak

Relative standard deviation: NMT 2.0%

Analysis

Sample: Sample solution

Calculate the percentage of isopropyl palmitate ($C_{19}H_{38}O_2$) in the portion of Isopropyl Palmitate taken:

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

r_U = peak area of isopropyl palmitate

r_T = sum of the peak areas of all the peaks, except the solvent peak

Acceptance criteria: NLT 90.0%

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

SPECIFIC TESTS

- [SPECIFIC GRAVITY \(841\)](#): 0.850–0.855
- [REFRACTIVE INDEX \(831\)](#): 1.435–1.438
- [FATS AND FIXED OILS, Acid Value \(401\)](#): NMT 1
- [FATS AND FIXED OILS, Iodine Value \(401\)](#): NMT 1
- [FATS AND FIXED OILS, Saponification Value \(401\)](#): 183–193

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- [USP REFERENCE STANDARDS \(11\)](#).
[USP Isopropyl Myristate RS](#)
[USP Isopropyl Palmitate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ISOPROPYL PALMITATE	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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