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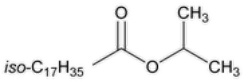
Add the following:

▲Isopropyl Isostearate



INS: Isooctadecanoic acid, 1-methylethyl ester contains mainly isomers of isopropyl branched stearates.

$C_{21}H_{42}O_2$ 326.56

Isooctadecanoic acid, 1-methylethyl ester CAS RN®: 68171-33-5.

DEFINITION

Isopropyl Isostearate is obtained by esterification of isostearic acid, which is a mixture mainly of saturated branched 18 carbon-chain (C18) fatty acids and linear hexadecanoic (C16:0) and octadecanoic acids (C18:0), with isopropyl alcohol.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197A** or **197F**.▲ (CN 1-May-2020) Disregard a weak absorption band at about 1780 cm^{-1}.

• **B.** It meets the requirements of the test for *Content of Isopropyl Fatty Esters*.

ASSAY

• **Content of Isopropyl Fatty Esters**

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

Reference solution: 2.0 mg/mL of isopropyl stearate in *n*-hexane

Sample solution: 5.0 mg/mL of Isopropyl Isostearate 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	21

Carrier gas: Helium

Flow rate: 1.5 mL/min

Injection volume: 2.0 µL

Injection type: Split injection, split ratio, 10:1

Run time: About 35 min

System suitability

Samples: *System suitability solution* and *Reference solution*

[NOTE—The relative retention times for isopropyl myristate, isopropyl palmitate, and isopropyl stearate are 0.8, 1.0, and 1.3, respectively.]

Suitability requirements

Resolution: NLT 6.0 between the isopropyl myristate and isopropyl palmitate peaks, *System suitability solution*

Tailing factor: NMT 2 for the isopropyl palmitate peak, *System suitability solution*

Relative standard deviation: NMT 2.0%, *System suitability solution*

Analysis

Samples: *System suitability solution*, *Reference solution*, and *Sample solution*

Identify the isopropyl fatty ester peaks in the chromatogram of the *Sample solution* by comparing the retention times of these peaks with those obtained in the chromatograms of the *System suitability solution* and *Reference solution*, and measure the peak areas for all of the fatty acid ester peaks in the chromatogram obtained from the *Sample solution*.

Calculate the percentage of each fatty acid ester component in the portion of Isopropyl Isostearate:

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

r_U = peak area for each individual fatty acid ester component

r_T = sum of the peak areas, excluding the solvent peak, from the *Sample solution*

Acceptance criteria

Sum of the contents of the isopropyl fatty esters eluting between isopropyl palmitate and isopropyl stearate (excluding isopropyl palmitate and isopropyl stearate)**:** NLT 65.0%

Sum of the contents of isopropyl myristate, isopropyl palmitate, and isopropyl stearate: NMT 11.0%

IMPURITIES

• **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%

SPECIFIC TESTS

• **FATS AND FIXED OILS ⟨401⟩, *Procedures, Acid Value*:** NMT 1.0, determined on 20.0 g

• **FATS AND FIXED OILS ⟨401⟩, *Procedures, Hydroxyl Value*:** NMT 5.0

• **FATS AND FIXED OILS ⟨401⟩, *Procedures, Iodine Value*:** NMT 3.0, determined on 3.0 g

• **FATS AND FIXED OILS ⟨401⟩, *Procedures, Peroxide Value*:** NMT 5.0

• **FATS AND FIXED OILS ⟨401⟩, *Procedures, Saponification Value*:** 165–180, determined on 2.0 g

• **WATER DETERMINATION ⟨921⟩, *Method I*:** NMT 0.1%, determined on 5.0 g[1]

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers. Store at room temperature.

Change to read:

• **USP REFERENCE STANDARDS ⟨11⟩**

▲USP Isopropyl Isostearate RS▲ (ERR 1-Oct-2018)

USP Isopropyl Myristate RS

USP Isopropyl Palmitate RS▲ (1S (NF36))

[1] Hydranal composite 5 is suitable.

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

Topic/Question	Contact	Expert Committee
ISOPROPYL ISOSTEARATE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(1)

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