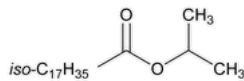


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Add the following:

▲Isopropyl Isostearate



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

C₂₁H₄₂O₂ 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 J](#): NMT 0.1%, determined on 5.0 g¹

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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