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Isostearyl Isostearate

DEFINITION

Isostearyl Isostearate is obtained by esterification of isostearic acid which is a mixture mainly of saturated branched 18 carbon-chain (C18) fatty acids, linear hexadecanoic (C16:0) and octadecanoic acids (C18:0), with isostearyl alcohol. It contains NLT 85.0% of isostearyl isostearate.

IDENTIFICATION

• **A. Ester**

Analysis 1: Proceed as directed in *Fats and Fixed Oils ⟨401⟩, Procedures, Saponification Value*.

Sample: 3 g

Analysis: Proceed as directed in the chapter. Heat under reflux for 1 h.

Acceptance criteria: 90–110

Analysis 2: Proceed as directed in *Fats and Fixed Oils ⟨401⟩, Procedures, Acid Value*.

Sample: Sample amount (see *Fats and Fixed Oils ⟨401⟩, Table 1*)

Acceptance criteria: NMT 6.0

• **B. Chromatographic Identity**

Analysis: Proceed as directed in the *Assay*.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Tetrahydrofuran

Reference solution: 2 mg/mL of isostearic acid in *Mobile phase*

Standard solution: 40 mg/mL of USP Isostearyl Isostearate RS in *Mobile phase*

Sample solution: 40 mg/mL of Isostearyl Isostearate in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Differential refractive index

Column: Two 7.5-mm × 30-cm columns in tandem; 3-µm packing L21

Temperatures

Column: 35°

Detector: 35°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

Run time: 30 min

System suitability

Samples: *Reference solution* and *Standard solution*

[Note—The relative retention times for isostearyl isostearate, isostearic acid, and isostearyl alcohol are 1.00, 1.07, and 1.09, respectively.]

Suitability requirements

Resolution: NLT 1.3 between the isostearyl isostearate peak and the adjacent peak at the retention time 1.09 relative to isostearyl isostearate, *Standard solution*

Relative standard deviation: NMT 2.0%, determined from the isostearyl isostearate peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of isostearyl isostearate in the portion of Isostearyl Isostearate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of isostearyl isostearate from the *Sample solution*

r_S = peak response of isostearyl isostearate from the *Standard solution*

C_S = concentration of USP Isostearyl Isostearate RS in the *Standard solution*

C_U = concentration of Isostearyl Isostearate in the *Sample solution*

Acceptance criteria: NLT 85.0%

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

SPECIFIC TESTS

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Hydroxyl Value***
Sample: 4 g
Analysis: Proceed as directed in the chapter. A sand bath can be used.
Acceptance criteria: NMT 25.0

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Iodine Value***
Sample: 3 g
Acceptance criteria: NMT 5.0

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Peroxide Value***
Sample: 3 g
Acceptance criteria: NMT 5.0

• **Water Determination ⟨921⟩, *Method I***
Sample: 3 g
Acceptance criteria: NMT 0.5%

• **Refractive Index ⟨831⟩:** 1.454–1.464 at 25°

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, protected from light and moisture. Store at room temperature, and avoid exposure to excessive heat.

• **USP Reference Standards ⟨11⟩**
USP Isostearyl Isostearate RS

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

Topic/Question	Contact	Expert Committee
ISOSTEARYL ISOSTEARATE	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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