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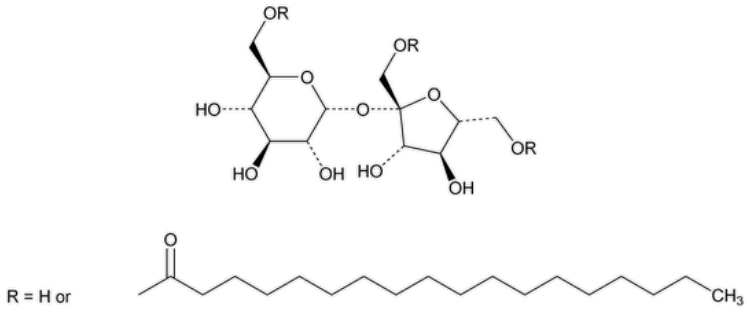
Sucrose Stearate



$C_{30}H_{56}O_{12}$ 608.76
$C_{48}H_{90}O_{13}$ 875.22
$C_{66}H_{124}O_{14}$ 1141.68

Sucrose monostearate;

Sucrose octadecanoate CAS RN®: 25168-73-4.

DEFINITION

Sucrose Stearate is a mixture of sucrose esters, mainly sucrose stearate, obtained by transesterification of stearic acid methyl esters derived from vegetable origin with sucrose. The manufacture of the fatty acid methyl esters includes a distillation step. The mono- and diesters requirements differ for the two types of sucrose stearate as set forth in the following table.

	Content of Monoesters (%)	Content of Diesters (%)	Sum of Triesters and Polyesters (%)
Type I	NLT 50.0	NMT 40.0	NMT 25.0
Type II	20.0–45.0	30.0–40.0	NMT 30.0

IDENTIFICATION

- **A.** It meets the requirements of the *Fatty Acid Composition* test.
- **B.** It meets the requirements of *Content of Monoesters, Diesters, Triesters, and Polyesters.*

ASSAY

- **Content of Monoesters, Diesters, Triesters, and Polyesters**

Mobile phase: Tetrahydrofuran

Sample solution: 15 mg/mL of Sucrose Stearate in tetrahydrofuran

Chromatographic system

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

Mode: LC, size-exclusion

Detector: Differential refractometer

Column: 7-mm × 60-cm; packing L21, 100 Å. [Note—Two 7-mm × 30-cm L21 columns may be used in place of one 60-cm column, provided system suitability requirements are met.]

Flow rate: 1.2 mL/min

Injection size: 20 µL

Analysis

Sample: *Sample solution*

[Note—The relative retention time with reference to the monoester peak (retention time is approximately 10 min) is about 0.92 for diesters, and about 0.90 for triesters and polyesters.]

[Note—Disregard solvent peaks and peaks having a signal-to-noise ratio less than 10.]

Calculate the percentage of monoesters in the portion of Sucrose Stearate taken:

$$\text{Result} = A \times (100 - D - S - E)/100$$

A = percentage of monoesters determined by peak normalization

D = percentage of free fatty acids, obtained by AV × 284.5/561.1, where AV is the acid value

S = percentage of free sucrose (see *Free Sucrose* in *Organic Impurities*)

E = percentage of water (see *Water Determination*, *Ia* in *Specific Tests*)

AV = acid value

Calculate the percentage of diesters in the portion of Sucrose Stearate taken:

$$\text{Result} = B \times (100 - D - S - E)/100$$

B = percentage of diesters determined by peak normalization

D = percentage of free fatty acids (above)

S = percentage of free sucrose (see *Free Sucrose* in *Organic Impurities*)

E = percentage of water (see *Water Determination*, *Ia* in *Specific Tests*)

Calculate the percentage of triesters and polyesters in the portion of Sucrose Stearate taken:

$$\text{Result} = C \times (100 - D - S - E)/100$$

C = percentage of triesters and polyesters determined by peak normalization

D = percentage of free fatty acids (above)

S = percentage of free sucrose (see *Free Sucrose* in *Organic Impurities*)

E = percentage of water (see *Water Determination*, *Ia* in *Specific Tests*)

• **Fatty Acid Composition:** Sucrose Stearate exhibits the following composition profiles of fatty acids, as determined in *Fats and Fixed Oils* ⟨401⟩, *Fatty Acid Composition*.

Fatty Acid	Percentage (%)
Lauric acid	NMT 3.0
Myristic acid	NMT 3.0
Palmitic acid	25.0–40.0
Stearic acid	55.0–75.0
Sum of the contents of palmitic acid and stearic acid	NLT 90.0

IMPURITIES

Inorganic Impurities

• **Fats and Fixed Oils,** *Acid Value* ⟨401⟩**:** NMT 6, determined on a 3-g sample. Use a freshly neutralized mixture of 2-propanol and water (2:1), and gently heat.

Organic Impurities

• **Procedure: Free Sucrose**

Solution A: 10 µg/mL of ammonium acetate in acetonitrile

Solution B: 10 µg/mL of ammonium acetate in tetrahydrofuran and water (90:10)

Diluent: Tetrahydrofuran and water (87.5:12.5)

System suitability solution: 500 µg/mL of USP Sucrose RS in *Diluent*

Standard solutions: 0.50, 1.0, 2.0, and 2.5 mg/mL of USP Sucrose RS in *Diluent*

Sample solution: 50 mg/mL of Sucrose Stearate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: Evaporative light-scattering. [NOTE—If the detector has different setting parameters, adjust the detector settings so as to comply with the *System Suitability* requirements.]

Carrier gas: Nitrogen

Detector temperature: 45°

Nebulizer temperature: 40°

Column: 4.6-mm × 0.25-m; packing L8

Injection size: 20 µL

Mobile phase and flow rate: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)	Flow Rate (mL/min)
1	100	0	1.0
8	0	100	1.0
7	0	100	1.0
0.01	0	100	2.5
15.99	0	100	2.5
1	100	0	2.5
3	100	0	1.0

System suitability

Sample: *System suitability solution*

[NOTE—The retention time for sucrose stearate is about 26 min.]

Suitability requirements

Signal-to-noise ratio: 10:1

Analysis

Samples: *Standard solutions* and *Sample solution*

Prepare a standard curve by plotting the peak response versus concentration of sucrose in the *Standard solution*. Calculate the quantity of free sucrose in the Sucrose Stearate taken.

Acceptance criteria: NMT 4.0%

SPECIFIC TESTS

• **WATER DETERMINATION, *Method Ia* ⟨921⟩:** NMT 4.0%, on a 0.20-g sample

• **TOTAL ASH**

Analysis: Heat a silica or platinum crucible to redness for 30 min, allow to cool in a desiccator, and weigh. Transfer a 1.0-g sample into a crucible. Dry at 100°–105° for 1 h and ignite to constant weight in a muffle furnace at 600 ± 25°, allowing the crucible to cool in a desiccator after each ignition. Flames should not be produced at any time during the procedure. If after prolonged ignition the ash still contains black particles, add hot water, pass through an ashless filter paper, and ignite the residue and the filter paper. Combine the filtrate with the ash, carefully evaporate to dryness, and ignite to constant weight.

Acceptance criteria: NMT 1.5%

ADDITIONAL REQUIREMENTS

• **LABELING:** Label to indicate whether it is Type I or Type II.

• **Packaging and Storage:** Preserve in a well-closed container. Protect from humidity and avoid high temperatures.

• **USP Reference Standards** ⟨11⟩
USP Sucrose RS

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

Topic/Question	Contact	Expert Committee
SUCROSE STEARATE	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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