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Add the following:

▲Sodium Lauroyl Sarcosinate

$C_{15}H_{28}NNaO_3$ 293.38

Glycine, *N*-methyl-*N*-(1-oxododecyl)-, sodium salt (1:1);

Sodium *N*-dodecanoyl-*N*-methylglycinate; CAS RN®: 137-16-6.

DEFINITION

Sodium Lauroyl Sarcosinate is a mixture of sodium *N*-acyl-*N*-methylglycinates, mainly consisting of NLT 92.0% and NMT 102.0% of sodium *N*-lauroyl-*N*-methylglycinate (sodium [dodecanoyl(methyl)amino]acetate) calculated on the anhydrous basis. It may contain a chelating agent.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A

• **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*.

• **C. Presence of Sodium**

Sample solution: Transfer 0.5 g of Sodium Lauroyl Sarcosinate in a silica crucible and ignite in a muffle furnace at 600 ± 25° for 1 h. Allow to cool to room temperature. Dissolve the residue in 10 mL of water. Use 0.5 mL of the solution so obtained as a *Sample solution*.

Methoxyphenylacetic solution: Dissolve 2.7 g of methoxyphenylacetic acid in 6 mL of 10% (w/w) tetramethylammonium hydroxide solution, and add 20 mL of absolute alcohol. Store in a polyethylene container.

Analyses: Perform the following 4 analyses in sequence.

Analysis 1: To the *Sample solution* add 1.5 mL of *Methoxyphenylacetic solution*, and cool in ice water for 30 min. Rub the inside of the test tube to initiate precipitation.

Acceptance criteria: A voluminous, white, crystalline precipitate is formed.

Analysis 2: Place the test tube in water at 20°, and stir for 5 min.

Acceptance criteria: The precipitate does not disappear.

Analysis 3: To the test tube, add 1 mL of a 100-mg/mL ammonia solution, prepared by diluting 41 g of stronger ammonia water with water to 100 mL.

Acceptance criteria: The precipitate dissolves completely.

Analysis 4: To the test tube, add 1 mL of a 158-mg/mL ammonium carbonate solution, and mix well.

Acceptance criteria: No precipitate is observed.

ASSAY

• **Procedure**

Solution A: 0.05% phosphoric acid, prepared by dissolving 1.0 mL of phosphoric acid in 2 L of water and mixing well

Solution B: Acetonitrile

Diluent: *Solution A* and *Solution B* (1:1)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	50	50
25	50	50
26	5	95
31	5	95
32	50	50
40	50	50

System suitability solution: 0.4 mg/mL of USP Sodium Lauroyl Sarcosinate RS and 20 µg/mL of USP Sodium Decanoyl Sarcosinate RS in *Diluent*

Standard solution: 0.4 mg/mL of USP Sodium Lauroyl Sarcosinate RS in *Diluent*

Sample solution: 0.4 mg/mL of Sodium Lauroyl Sarcosinate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

Column: 4.6-mm × 10-cm; 2.7-µm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: NLT 40 min

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The typical retention time for sodium lauroyl sarcosinate is about 7 min. The relative retention times for sodium decanoyl sarcosinate and sodium lauroyl sarcosinate are 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8.0 between sodium lauroyl sarcosinate and sodium decanoyl sarcosinate, *System suitability solution*

Tailing factor: 0.8–1.5, *Standard solution*

Relative standard deviation: NMT 0.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sodium lauroyl sarcosinate ($C_{15}H_{28}NNaO_3$) in the portion of Sodium Lauroyl Sarcosinate taken:

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

r_U = peak response of sodium lauroyl sarcosinate from the *Sample solution*

r_S = peak response of sodium lauroyl sarcosinate from the *Standard solution*

C_S = concentration of USP Sodium Lauroyl Sarcosinate RS in the *Standard solution* (mg/mL)

C_U = concentration of Sodium Lauroyl Sarcosinate in the *Sample solution* (mg/mL)

Acceptance criteria: 92.0%–102.0% on the anhydrous basis

IMPURITIES

• **LIMIT OF SODIUM DECANOYL SARCOSINATE AND SODIUM MYRISTOYL SARCOSINATE**

Solution A, Solution B, Diluent, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 2 µg/mL of USP Sodium Decanoyl Sarcosinate RS and 6 µg/mL of USP Sodium Myristoyl Sarcosinate RS in *Diluent*

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for sodium decanoyl sarcosinate, sodium lauroyl sarcosinate, and sodium myristoyl sarcosinate are 0.4, 1.0, and 2.7, respectively.]

Suitability requirements

Resolution: NLT 8.0 between sodium lauroyl sarcosinate and sodium decanoyl sarcosinate, *System suitability solution*

Relative standard deviation: NMT 5%, *Standard solution*

Signal-to-noise ratio: NLT 40, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Based on the *Standard solution*, identify the peaks of sodium decanoyl sarcosinate and sodium myristoyl sarcosinate. Compare peak areas of sodium decanoyl sarcosinate and sodium myristoyl sarcosinate in the *Standard solution* and the *Sample solution*.

Acceptance criteria

Sodium decanoyl sarcosinate: The peak area of sodium decanoyl sarcosinate in the *Sample solution* is NMT the peak area of sodium decanoyl sarcosinate in the *Standard solution*, corresponding to NMT 0.5% of sodium decanoyl sarcosinate in Sodium Lauroyl Sarcosinate.

Sodium myristoyl sarcosinate: The peak area of sodium myristoyl sarcosinate in the *Sample solution* is NMT the peak area of sodium myristoyl sarcosinate in the *Standard solution*, corresponding to NMT 1.5% of sodium myristoyl sarcosinate in Sodium Lauroyl Sarcosinate.

- **Limit of Sodium Sarcosinate**

Solution A: Add 3.0 mL of glacial acetic acid and 1.0 mL of triethylamine to 1 L of water, and mix well. Adjust with 1 M sodium hydroxide solution to a pH of 4.2.

Solution B: Acetonitrile

Borate buffer: Weigh 0.62 g of boric acid and dissolve in 100 mL of water. Adjust with 1 M sodium hydroxide solution to a pH of 9.0. This is a 0.1 M borate buffer.

FMOC-Cl solution: 30 µg/mL of 9-fluorenylmethyl chloroformate (FMOC-Cl) in *Solution B*

Diluent: *Solution B* and water (2:3)

Mobile phase: See *Table 2*.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0.0	60	40
2.0	60	40
2.5	5	95
8.5	5	95
9.0	60	40
13.0	60	40

System suitability solution A: 1.0 mg/mL of USP Sodium Lauroyl Sarcosinate RS, 8 µg/mL of sarcosine, and 10 µg/mL of 9-fluorenemethanol in *Diluent*

System suitability solution B: Add 0.1 mL of *Borate buffer* and 0.5 mL of *FMOC-Cl solution* to 0.4 mL of *System suitability solution A*, and mix well. Use within 24 h.

Standard solution A: 0.8 µg/mL of sarcosine in *Diluent*

Standard solution B: Add 0.1 mL of *Borate buffer* and 0.5 mL of *FMOC-Cl solution* to 0.4 mL of *Standard solution A*, and mix well. Use within 24 h.

Sample solution A: 1.0 mg/mL of Sodium Lauroyl Sarcosinate in *Diluent*

Sample solution B: Add 0.1 mL of *Borate buffer* and 0.5 mL of *FMOC-Cl solution* to 0.4 mL of *Sample solution A*, and mix well. Use within 24 h.

Chromatographic system

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

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 10-cm; 2.7-µm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: NLT 13 min

System suitability

Samples: *System suitability solution B* and *Standard solution B*

[NOTE—The relative retention times for the FMOC derivative of sarcosine (FMOC-sarcosine) and 9-fluorenemethanol are 1.0 and 1.8, respectively.]

Suitability requirements

Resolution: NLT 3 between the FMOC derivative of sarcosine (FMOC-sarcosine) and 9-fluorenemethanol, *System suitability solution B*

Relative standard deviation: NMT 5% for the peak of the FMOC derivative of sarcosine (FMOC-sarcosine), *Standard solution B*

Signal-to-noise ratio: NLT 10 for the peak of the FMOC derivative of sarcosine (FMOC-sarcosine), *Standard solution B*

Analysis

Samples: *Standard solution B* and *Sample solution B*

Based on *Standard solution B*, identify the peak of the FMOC derivative of sarcosine (FMOC-sarcosine).

Calculate the percentage of sodium sarcosinate in the portion of Sodium Lauroyl Sarcosinate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak area of FMOC-sarcosine from *Sample solution B*

r_S = peak area of FMOC-sarcosine from *Standard solution B*

C_S = concentration of FMOC-sarcosine in *Standard solution B* (mg/mL)

C_U = concentration of Sodium Lauroyl Sarcosinate in *Sample solution B* (mg/mL)

M_{r1} = molecular weight of sodium sarcosinate, 111.08

M_{r2} = molecular weight of sarcosine, 89.09

Acceptance criteria: NMT 0.2%

- **LIMIT OF SODIUM LAURATE**

Solution A, Solution B, Diluent, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution A: 0.072 mg/mL of USP Lauric Acid RS in *Diluent*

Standard solution B: 0.36 mg/mL of USP Lauric Acid RS in *Diluent*

Sample solution: 8.0 mg/mL of Sodium Lauroyl Sarcosinate in *Diluent*

System suitability

Samples: *System suitability solution*, *Standard solution A*, and *Standard solution B*

[NOTE—The relative retention times for sodium decanoyl sarcosinate, sodium lauroyl sarcosinate, and sodium laurate are 0.4, 1.0, and 1.9, respectively.]

Suitability requirements

Resolution: NLT 8.0 between sodium lauroyl sarcosinate and sodium decanoyl sarcosinate, *System suitability solution*

Relative standard deviation: NMT 5%, *Standard solution B*

Signal-to-noise ratio: NLT 10, *Standard solution A*

Analysis

Samples: *Standard solution B* and *Sample solution*

Calculate the percentage of sodium laurate in the portion of Sodium Lauroyl Sarcosinate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak area of lauric acid from the *Sample solution*

r_S = peak area of lauric acid from *Standard solution B*

C_S = concentration of USP Lauric Acid RS in *Standard solution B* (mg/mL)

C_U = concentration of Sodium Lauroyl Sarcosinate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of sodium laurate, 222.30

M_{r2} = molecular weight of lauric acid, 200.32

Acceptance criteria: NMT 5.0%

- **Limit of Sodium Chloride**

Sample: 500 mg of Sodium Lauroyl Sarcosinate

Analysis: Dissolve the *Sample* in 50 mL of a mixture of equal volumes of alcohol and water. Add 10 mL of nitric acid and titrate with 0.005 M silver nitrate, determining the endpoint potentiometrically.[1]

Calculate the percentage of sodium chloride in the portion of Sodium Lauroyl Sarcosinate taken:

$$\text{Result} = [(M \times V \times M_r)/W] \times 100$$

M = molarity of the silver nitrate solution (mmol/mL)

V = volume of 0.005 M silver nitrate used (mL)

M_r = molecular weight of sodium chloride, 58.44 mg/mmol

W = weight of the *Sample* (mg)

Acceptance criteria: NMT 0.5%

- **Limit of Sodium Sulfate**

Sample: 300 mg of Sodium Lauroyl Sarcosinate

Buffer solution: Add 60.0 mL of 2-propanol to 15.0 mL of acetic acid (300 mg/mL of glacial acetic acid in water). Adjust with stronger ammonia water to a pH of 3.7, and dilute with water to 100.0 mL.

Barium perchlorate solution: Dilute 10.0 mL of 0.05 M barium perchlorate solution with *Buffer solution* to 100 mL. The concentration is 0.005 M.

Analysis: In a 150-mL borosilicate-glass beaker dissolve the *Sample* in 20 mL of water. Add 0.3 mL of a 1-mg/mL naphtharson solution, 1.0 mL of perchloric acid, and 70.0 mL of 2-propanol.

Degas the solution under vacuum for 30 s or use an ultrasonic bath for 2 min and then titrate with *Barium perchlorate solution*.

Determine the endpoint using a suitable autotitrator equipped with an optrode or phototrode at about 520 nm and at 25°.[2] Use a breakpoint to define the end of the titration. Adjust the stirrer speed to avoid the formation of bubbles.

Calculate the percentage of sodium sulfate in the portion of Sodium Lauroyl Sarcosinate taken:

$$\text{Result} = [(M \times V \times M_r)/W] \times 100$$

M = molarity of the *Barium perchlorate solution* (mmol/mL)

V = volume of *Barium perchlorate solution* used (mL)

M_r = molecular weight of sodium sulfate, 142.04 mg/mmol

W = weight of the *Sample* (mg)

Acceptance criteria: NMT 1.5%

SPECIFIC TESTS

- **pH** ⟨791⟩

Sample solution: Dissolve 3.0 g in carbon dioxide-free water and dilute with water to 100 mL.

Acceptance criteria: 7.5–8.5

- **Water Determination** ⟨921⟩, *Method I*: NMT 5.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at room temperature.
- **Labeling:** Label to indicate the name and amount of any added chelating agent.
- **USP Reference Standards** ⟨11⟩

USP Lauric Acid RS

USP Sodium Decanoyl Sarcosinate RS

USP Sodium Lauroyl Sarcosinate RS

USP Sodium Myristoyl Sarcosinate RS▲ (NF 1-Dec-2021)

[1] Electrode DM141-SC is suitable.

[2] Optrode from Metrohm or DP5 phototrode from Mettler.

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

Topic/Question	Contact	Expert Committee
SODIUM LAUROYL SARCOSINATE	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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