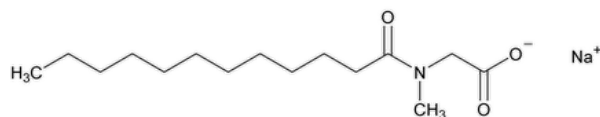


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Dec-2021
 Document Type: NF Monographs
 DocId: GUID-C7A73B1F-B512-47E4-A7F7-2246B9E3F275_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M7202_02_01
 DOI Ref: n9oto

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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 $600 \pm 25^\circ$ 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