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Sodium Lauryl Sulfate

Portions of this monograph that are national *USP* text, and are not part of the harmonized text, are marked with symbols (◆) to specify this fact.

Sulfuric acid monododecyl ester sodium salt;

Sodium monododecyl sulfate

CAS RN®: 151-21-3.

DEFINITION

Sodium Lauryl Sulfate is a mixture of sodium alkyl sulfates consisting chiefly of sodium lauryl sulfate ($C_{12}H_{25}NaO_4S$). It contains NLT 85.0% of sodium alkyl sulfates calculated as sodium lauryl sulfate ($C_{12}H_{25}NaO_4S$).

IDENTIFICATION

Change to read:

• ▲▲ (NF 1-MAY-2021) **A. SPECTROSCOPIC IDENTIFICATION TESTS ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197K▲▲ (NF 1-May-2021)

• **B. SODIUM**

Potassium pyroantimonate solution: To 2 g of potassium pyroantimonate add 100 mL of water. Boil the solution for about 5 min, cool quickly, and add 10 mL of a solution of potassium hydroxide (3 in 20). Allow to stand for 24 h, and filter.

Sample: 2.5 g

Analysis: Place the *Sample* in a silica or platinum crucible, and add 2 mL of 10 N sulfuric acid. Heat on a water bath, then cautiously raise the temperature progressively over an open flame. Ignite, preferably in a muffle furnace, at 600 ± 25°. Continue heating until all black particles have disappeared. Cool, add a few drops of 2 N sulfuric acid, and heat and ignite as above. Add a few drops of ammonium carbonate TS, evaporate to dryness, and ignite as above. Cool, dissolve the residue in 50 mL of water, and mix. To a 2-mL portion of this solution, add 4 mL of *Potassium pyroantimonate solution*. If necessary, rub the inside of the test tube with a glass rod.

Acceptance criteria: A white, crystalline precipitate is formed.

• **C. SULFATE**

Sample: Solution (1 in 10)

Analysis: After acidification with hydrochloric acid and boiling for 20 min, no precipitate is formed. Add barium chloride TS; a white precipitate is produced.

Acceptance criteria: Meets the requirements

Delete the following:

▲• **D.**

Sample: 0.1 g

Analysis: Dissolve the *Sample* in 10 mL of water and shake.

Acceptance criteria: A copious foam is formed.▲ (NF 1-May-2021)

Delete the following:

▲• **E.**

Sample: Solution prepared for *Identification D*

Analysis: To 0.1 mL of the *Sample*, add 0.1 mL of a 1-g/L solution of methylene blue and 2 mL of diluted sulfuric acid. Add 2 mL of methylene chloride and shake.

Acceptance criteria: An intense blue color develops in the methylene chloride layer.▲ (NF 1-May-2021)

ASSAY

Change to read:

• **Content of Sodium Alkyl Sulfates**

▲Dimidium bromide–sulfan blue mixed solution: Dissolve separately 0.5 g of dimidium bromide and 0.25 g of sulfan blue in 30 mL of a hot solution of 10% ethanol in water, combine these solutions, and dilute with 10% ethanol to 250 mL. Mix 20 mL of this solution with 20 mL of a 14.0% (v/v) solution of sulfuric acid previously diluted with about 250 mL of water, and dilute with water to 500 mL.▲ (NF 1-May-2021)

Sample: ▲1.15 g▲ (NF 1-May-2021) of Sodium Lauryl Sulfate

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.004 M benzethonium chloride VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in water, warming if necessary, and dilute with water to exactly 1000.0 mL. ▲Mix 20.0 mL of the solution with 15 mL of methylene chloride and 10 mL of *Dimidium bromide–sulfan blue mixed solution*.▲ (NF 1-May-2021) Titrate with *Titrant*, shaking vigorously and allowing the layers to separate before each addition, until ▲the pink color of the methylene chloride layer is completely discharged and a greyish-blue color is obtained.▲ (NF 1-May-2021) One milliliter of *Titrant* is equivalent to 1.154 mg of sodium alkyl sulfates, calculated as sodium lauryl sulfate ($C_{12}H_{25}NaO_4S$).

Acceptance criteria: NLT 85.0%, calculated as sodium lauryl sulfate ($C_{12}H_{25}NaO_4S$)

IMPURITIES

Change to read:

• **Sodium Chloride**

Fluorescein sodium solution: Dissolve 0.2 g of fluorescein sodium in water to 100 mL.

Dilute nitric acid: Dilute 105 mL of nitric acid with water to 1000 mL.

Sample solution: 100 mg/mL of Sodium Lauryl Sulfate in water

Analysis: Neutralize 50 mL of *Sample solution* with *Dilute nitric acid*, using litmus paper as the indicator, if necessary. Add exactly 5.0 mL of 0.1 N sodium chloride and titrate, ▲under vigorous stirring (to disperse silver chloride),▲ (NF 1-May-2021) with 0.1 N silver nitrate VS (indicator: 2 drops of *Fluorescein sodium solution*) to the first appearance of turbidity with solution color change from yellow-green to orange through yellow. Perform a blank determination, and make any necessary correction. Each milliliter of 0.1 N silver nitrate is equivalent to 5.844 mg of sodium chloride.

Acceptance criteria: The combined content of sodium chloride and sodium sulfate is NMT 8.0%.

Change to read:

• **Sodium Sulfate**

Sample solution: 100 mg/mL of Sodium Lauryl Sulfate in water

Analysis: To 10 mL of *Sample solution*, add 100 mL of alcohol and heat at a temperature just below the boiling point for 2 h. Pass through a glass ▲or porcelain▲ (NF 1-May-2021) filter ▲(pore size equivalent to 4–10 µm)▲ (NF 1-May-2021) while hot, and wash with 100 mL of boiling alcohol. Dissolve the precipitate by washing with 150 mL of water, collecting the washings in a beaker. Add 10 mL of diluted hydrochloric acid, heat to boiling, add 25 mL of barium chloride TS, and allow to stand overnight. Collect the precipitate ▲by filtration through a filter (maximum pore size of 16 µm)▲ (NF 1-May-2021) and wash with water until the last washing shows no opalescence with ▲0.1 N silver nitrate VS▲ (NF 1-May-2021) . Dry the precipitate, ignite to constant mass between 500° and 600° by raising the temperature gradually, and weigh as barium sulfate ($BaSO_4$; 233.39).

$$\text{Amount (mg) of sodium sulfate } (Na_2SO_4) = \text{amount (mg) of barium sulfate } (BaSO_4) \times 0.6086$$

Acceptance criteria: The combined content of sodium chloride and sodium sulfate is NMT 8.0%.

SPECIFIC TESTS

• **Alkalinity**

Sample solution: Dissolve 1.0 g in 100 mL of water, add 0.1 mL of phenol red TS, and titrate with 0.10 N hydrochloric acid.

Acceptance criteria: NMT 0.5 mL for neutralization

• **Total Alcohols:** Transfer 5 g to an 800-mL Kjeldahl flask, and add 150 mL of water, 50 mL of hydrochloric acid, and a few boiling chips. Attach a reflux condenser to the Kjeldahl flask, heat carefully to avoid excessive frothing, and boil for 4 h. Cool the flask, rinse the condenser with ether, collecting the ether in the flask, and transfer the contents to a 500-mL separator, rinsing the flask twice with ether and adding the washings to the separator. Extract the solution with two 75-mL portions of ether, evaporate the combined ether extracts in a tared beaker on a steam bath, dry the residue at 105° for 30 min, cool, and weigh.

Acceptance criteria: The residue represents the total alcohols and is NLT 59.0% of the weight of Sodium Lauryl Sulfate taken.

• **Unsulfated Alcohols**

Sample solution: Dissolve 10 g in 100 mL of water, and add 100 mL of alcohol.

Analysis: Transfer the solution to a separator, and extract with three 50-mL portions of petroleum ether. If an emulsion forms, sodium chloride may be added to promote separation of the two layers. Wash the combined petroleum ether extracts with three 50-mL portions of water, and dry with anhydrous sodium sulfate. Filter the petroleum ether extract into a tared beaker. Evaporate on a water bath until the odor of petroleum ether no longer is perceptible, dry the residue at 105° for 30 min, cool, and weigh.

Acceptance criteria: The weight of the residue is NMT 4.0% of the weight of Sodium Lauryl Sulfate taken.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards** ⟨11⟩

USP Sodium Lauryl Sulfate RS

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

Topic/Question	Contact	Expert Committee
SODIUM LAURYL SULFATE	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

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