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Sodium Stearate

Octadecanoic acid, sodium salt;
Sodium stearate
CAS RN®: 822-16-2.

DEFINITION

Sodium Stearate is a compound of sodium with a mixture of solid organic acids obtained from sources of vegetable or animal origin and consists mainly of variable proportions of sodium stearate ($C_{18}H_{35}NaO_2$) and sodium palmitate ($C_{16}H_{31}NaO_2$). The content of stearic acid in the fatty acid fraction is NLT 40.0% of the total content. The sum of stearic acid and palmitic acid in the fatty acid fraction is NLT 90.0% of the total content. Sodium stearate contains small amounts of the sodium salts of other fatty acids.

IDENTIFICATION

• **A.**

Analysis: Heat a small quantity of Sodium Stearate in a crucible over a flame until it fuses. Continue heating the sample until it decomposes with emission of flammable vapors that should burn when ignited. Moisten the residue with water, and test with red litmus paper. The paper must turn blue. Add a small amount of acid to the crucible, and observe the solution effervesce. The solution must impart an intense yellow color to a nonluminous flame.

Acceptance criteria: Meets the requirements

• **B.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Boron trifluoride–methanol solution: 140 g/L of boron trifluoride in methanol

Sample solution: Dissolve 100 mg of Sodium Stearate in a small conical flask, fitted with a suitable reflux attachment, with 5 mL of *Boron trifluoride–methanol solution*. Boil under reflux for 10 min. Add 4.0 mL of *n*-heptane through the condenser, and boil again under reflux for 10 min. Allow to cool. Add 20 mL of a saturated solution of sodium chloride. Shake, and allow the layers to separate. Remove about 2 mL of the organic layer, and dry it over 0.2 g of anhydrous sodium sulfate. Dilute 1.0 mL of this solution with *n*-heptane to 10.0 mL.

Standard solution: Prepare as directed in the *Sample solution* using 50 mg of USP Stearic Acid RS and 50 mg of USP Palmitic Acid RS.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 30-m × 0.32-mm fused silica; 0.5-µm layer of phase G16

Temperatures

Injector: 220°

Detector: 260°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
70	—	70	2
70	5	240	5

Carrier gas: Helium, passed through a bed of molecular sieve for drying, if necessary

Flow rate: 2.4 mL/min

Injection type: Splitless

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 5.0 between the methyl palmitate and methyl stearate peaks. [NOTE—The relative retention times for methyl palmitate and methyl stearate are about 0.9 and 1.0, respectively.]

Relative standard deviation: NMT 3.0% for the methyl stearate and methyl palmitate peaks; NMT 1.0% for the ratio of the peak areas of methyl palmitate to the peak areas of methyl stearate, from 6 replicate injections

Analysis: Calculate the percentage of stearic acid ($C_{18}H_{36}O_2$) in the fatty acid fraction of the sample taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area due to methyl stearate

r_T = sum of all the peak areas, excluding the solvent peak

Calculate the percentage of palmitic acid ($C_{16}H_{32}O_2$) in the fatty acid fraction of the sample taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area due to methyl palmitate

r_T = sum of all the peak areas, excluding the solvent peak

Acceptance criteria

Stearic acid: NLT 40.0%

Sum of stearic acid and palmitic acid: NLT 90.0%

SPECIFIC TESTS

- **ACIDITY**

Sample solution: Heat 50 mL of alcohol to the same temperature, ±5°, as that attained when the pink endpoint is reached in the titration of the sample specimen. Add 3 drops of phenolphthalein TS and sufficient 0.020 N sodium hydroxide to produce a faint pink color. Add 2.00 g of Sodium Stearate, and dissolve with the aid of a small amount of heat. No pink color is produced.

Analysis: Titrate the solution with 0.020 N sodium hydroxide until a pink color is produced.

Acceptance criteria: 1.00–4.25 mL of 0.020 N sodium hydroxide is required (0.28%–1.2% as stearic acid).

- **LOSS ON DRYING** ⟨731⟩

Sample: Tare a beaker containing 1 g of washed sand, previously dried at 105°, add 500 mg of Sodium Stearate, and again weigh.

Analysis: To the *Sample* add 10 mL of alcohol, and evaporate at 80° to dryness. Dry at 105° for 4 h.

Acceptance criteria: NMT 5.0%

- **FATS AND FIXED OILS,** *Acid Value* ⟨401⟩

Sample: 1 g of the fatty acids obtained as follows. Dissolve 25 g of Sodium Stearate in 300 mL of hot water, add 60 mL of 2 N sulfuric acid, and heat the solution, with frequent stirring, until the separated fatty acid layer is clear. Wash the fatty acids with boiling water until they are free from sulfate, collect in a small beaker, and warm on a steam bath until the water has settled and the fatty acids are clear. Allow the acids to cool, pour off the water layer, then melt the acids, filter into a dry beaker while hot, and dry at 105° for 20 min.

Acceptance criteria: 196–211

• **Fats and Fixed Oils,** *Iodine Value* ⟨401⟩

Sample: The fatty acids obtained in *Fats and Fixed Oils, Acid Value* ⟨401⟩

Acceptance criteria: NMT 4.0

• **Alcohol-Insoluble Substances**

Sample: 1.0 g of Sodium Stearate

Analysis: Reflux the *Sample* with 25 mL of alcohol until it dissolves completely.

Acceptance criteria: The resulting solution is clear or NMT slightly opalescent.

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Label it to indicate the content of stearic acid in the fatty acid fraction and to indicate the fatty acids used to produce sodium stearate are from sources of vegetable or animal origin.

• **USP Reference Standards** ⟨11⟩

USP Palmitic Acid RS

USP Stearic Acid RS

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

Topic/Question	Contact	Expert Committee
SODIUM 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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