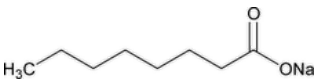
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: NF Monographs
DocId: GUID-9C4979C6-70B8-4A56-A643-5D9B56890EDD_3_en-US
DOI: https://doi.org/10.31003/USPNF_M76000_03_01
DOI Ref: 27ab5

Sodium Caprylate



$C_8H_{15}NaO_2$ 166.19

Sodium octanoate CAS RN®: 1984-06-1.

DEFINITION

Sodium Caprylate contains NLT 99.0% and NMT 101.0% of sodium caprylate ($C_8H_{15}NaO_2$), calculated on the anhydrous basis.

IDENTIFICATION

• **A.** The retention time of the major peak of *Sample solution A* corresponds to that of the *Standard solution*, as obtained in the test for *Chromatographic Purity* in *Impurities*.

• **B.**

Methoxyphenylacetic reagent: Dissolve 2.7 g of methoxyphenylacetic acid in 6 mL of 10% tetramethylammonium hydroxide solution in methanol, and add 20 mL of alcohol. Store in a polyethylene container.

Sample solution: 20 mg

Analysis: Dissolve the *Sample* in 0.5 mL of water, add 1.5 mL of *Methoxyphenylacetic reagent*, and cool in ice water for 30 min. A voluminous, white, crystalline precipitate is formed. Place in water at 20°, and stir for 5 min. The precipitate does not disappear. Add 1 mL of ammonia TS. The precipitate dissolves completely. Add 1 mL of ammonium carbonate solution (160 mg/mL).

Acceptance criteria: No precipitate is formed.

ASSAY

• **Procedure**

Sample: 150 mg

Blank: Glacial acetic acid

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis: Transfer the *Sample* to a 125-mL volumetric flask, and dissolve in 50 mL of glacial acetic acid. Titrate with *Titrant*. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 16.62 mg of sodium caprylate ($C_8H_{15}NaO_2$).

Acceptance criteria: 99.0%–101.0% on the anhydrous basis

IMPURITIES

• **Chromatographic Purity**

Standard solution: 1.0 mg/mL of USP Caprylic Acid RS in ethyl acetate

Sample solution A: Dissolve 116 mg of Sodium Caprylate in 5 mL of water, add 1 mL of dilute sulfuric acid (1 in 35), and extract with 10 mL of ethyl acetate. Separate the organic layer, and dry it over anhydrous sodium sulfate.

Sample solution B: Dilute 1.0 mL of *Sample solution A* with ethyl acetate to 100 mL, transfer 5.0 mL of the solution obtained, and dilute with ethyl acetate to 50 mL.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m fused silica; coated with a 0.25-µm layer of phase G25

Temperatures

Injection port: 250°

Detector: 250°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	—	100	1
100	5	220	10

Flow rate: 1.5 mL/min

Carrier gas: Helium

Injection volume: 1 µL

Injection type: Split ratio, 100:1

System suitability

Sample: *Sample solution B*

Suitability requirements

Signal-to-noise ratio: NLT 5

Analysis

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

Disregard any peaks with an area less than half of the area of the principal peak from *Sample solution B* and any peak due to the solvent. Calculate the percentage of each impurity in the portion of Sodium Caprylate taken:

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

r_U = peak response of the individual impurity

r_T = sum of all the peak responses

Acceptance criteria

Individual impurities: NMT 0.3%

Total impurities: NMT 0.5%

SPECIFIC TESTS

- **Appearance of Solution**

Standard stock solution: Combine 30.0 mL of ferric chloride CS, 30.0 mL of cobaltous chloride CS, and 24.0 mL of cupric sulfate CS, and dilute with 1% (w/v) hydrochloric acid to 100.0 mL.

Standard solution: Dilute 1.0 mL of *Standard stock solution* with 1% (w/v) hydrochloric acid to 100.0 mL.

Sample solution: Dissolve 2.5 g of Sodium Caprylate in 25.0 mL of freshly boiled and cooled water.

Acceptance criteria: The *Sample solution* is clear and colorless, or not more intensely colored than the *Standard solution*.

- **pH** ⟨791⟩

Sample solution: Use the *Sample solution* in the test for *Appearance of Solution*.

Acceptance criteria: 8.0–10.5

- **Water Determination,** *Method I* ⟨921⟩**:** NMT 3.0%

ADDITIONAL REQUIREMENTS

- **USP Reference Standards** ⟨11⟩

USP Caprylic Acid RS

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

Topic/Question	Contact	Expert Committee
SODIUM CAPRYLATE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 33(3)

Current DocID: GUID-9C4979C6-70B8-4A56-A643-5D9B56890EDD_3_en-US
Previous DocID: GUID-9C4979C6-70B8-4A56-A643-5D9B56890EDD_1_en-US
DOI: https://doi.org/10.31003/USPNF_M76000_03_01
DOI ref: 27ab5