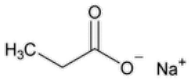
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2022
Document Type: NF Monographs
DocId: GUID-E7FACD22-923A-424A-9B3A-AB743AEEFF6D_5_en-US
DOI: https://doi.org/10.31003/USPNF_M77180_05_01
DOI Ref: 01ond

Sodium Propionate

Change to read:

▲



▲ (NF 1-Dec-2022)

$C_3H_5NaO_2$ 96.06

Propanoic acid, sodium salt▲▲ (NF 1-Dec-2022) ;

Sodium propionate ▲▲ (NF 1-Dec-2022) CAS RN®: 137-40-6.

Change to read:

DEFINITION

Sodium Propionate, dried at 105° for 2 h, contains ▲NLT 98.0% and NMT 102.0%▲ (NF 1-Dec-2022) of sodium propionate ($C_3H_5NaO_2$).

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K
  Analysis: Perform test on an undried sample.
  Acceptance criteria: Meets the requirements
- **B. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium***
  Sample solution: 1 in 20
  Acceptance criteria: Meets the requirements

Add the following:

▲- **C. Chromatographic Identity**
  Analysis: Examine the chromatograms obtained in the *Assay*.
  Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*.▲ (NF 1-Dec-2022)

ASSAY

Change to read:

- **Procedure**
  ▲**Solution A:** 10 mM potassium phosphate, monobasic, with the pH adjusted to 2.5 using phosphoric acid
  Solution B: Acetonitrile
  Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
3.0	100	0
15.0	70	30

Time (min)	Solution A (%)	Solution B (%)
25.0	50	50
26.0	100	0
35.0	100	0

Diluent: 2% (v/v) phosphoric acid in water

System suitability solution: 2.5 mg/mL of USP Sodium Propionate RS and 0.01 mg/mL of sodium acrylate in *Diluent*

Standard solution: 2.5 mg/mL of USP Sodium Propionate RS in *Diluent*

Sample solution: Dry Sodium Propionate at 105° for 2 h. After the sample cools to room temperature in a desicooler or an equivalent device, weigh the sample, and prepare a solution of 2.5 mg/mL in *Diluent*.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm column; 5-µm packing L1

Column temperature: 45°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

Run time: 35 min

System suitability

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

[Note—The approximate relative retention times for related substances are listed in *Table 2*.]

Suitability requirements

Resolution: NLT 1.5 between the sodium propionate peak and the sodium acrylate peak, *System suitability solution*

Tailing factor: NMT 2, determined from the sodium propionate peak, *Standard solution*

Relative standard deviation: NMT 1%, determined from the sodium propionate peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of Sodium Propionate in the portion of sample taken:

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

r_U = peak area of sodium propionate from the *Sample solution*

r_S = peak area of sodium propionate from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0%▲ (NF 1-Dec-2022)

Add the following:

▲IMPURITIES

• **Organic Impurities**

Mobile phase, Diluent, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.01 mg/mL of USP Sodium Propionate RS in *Diluent*

Standard solution: 0.02 mg/mL of USP Sodium Propionate RS in *Diluent*

Sample solution: 20 mg/mL of Sodium Propionate in *Diluent*

System suitability

Samples: *System suitability solution*, *Sensitivity solution*, and *Standard solution*.

[Note—The approximate relative retention times for related substances are listed in *Table 2*.]

Table 2

Name	Relative Retention Time
Sodium acetate	0.5
Sodium acrylate	0.95
Sodium propionate	1.0

Suitability requirements

Resolution: NLT 1.5 between the sodium propionate peak and the sodium acrylate peak, *System suitability solution*

Relative standard deviation: NMT 5.0%, determined from the sodium propionate peak, *Standard solution*

Signal-to-noise ratio: NLT 10, determined from the sodium propionate peak, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—The peak eluting at RRT 0.3 is sodium ion peak. This peak and the peaks eluting before it are exclusive from integration. These peaks are not from organic impurities of sodium propionate.]

Calculate the percentage of each individual impurity in the portion of sample taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak area of each individual impurity from the *Sample solution*

r_S = peak area of sodium propionate from the *Standard solution*

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

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

F = relative response factor (see *Table 3*)

Acceptance criteria: See *Table 3*.

Table 3

Name	Relative Response Factor	Acceptance Criteria, NMT (%)
Sodium acetate	1.0	0.3
Sodium acrylate	95.3	0.1
Sodium propionate	—	—
Any unidentified individual impurity	1.0	0.1
Total impurities	—	1.0▲ (NF 1-Dec-2022)

SPECIFIC TESTS

- **WATER DETERMINATION ⟨921⟩, *Method I*:** NMT 1.0%
- **ALKALINITY**

Sample solution: 2.0 g of Sodium Propionate in 20 mL of water

Analysis: Add phenolphthalein TS to the *Sample solution*.

Acceptance criteria: If a pink color is produced, it is discharged by 0.60 mL of 0.10 N sulfuric acid.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Sodium Propionate RS

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

Topic/Question	Contact	Expert Committee
SODIUM PROPIONATE	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. 46(6)

Current DocID: GUID-E7FACD22-923A-424A-9B3A-AB743AEEFF6D_5_en-US
DOI: https://doi.org/10.31003/USPNF_M77180_05_01
DOI ref: 01ond