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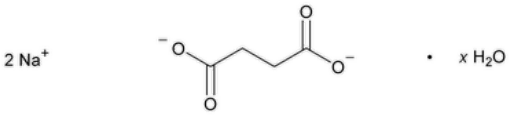
Sodium Succinate



INS: x = 0 or 6

$NaOOC\text{-}CH_2CH_2\text{-}COONa$ ($C_4H_4Na_2O_4$) 162.05

Anhydrous disodium 1,4-butanedioate;

Anhydrous butanedioic acid disodium salt CAS RN®: 150-90-3.

$NaOOC\text{-}CH_2CH_2\text{-}COONa \cdot 6H_2O$ ($C_4H_4Na_2O_4 \cdot 6H_2O$) 270.14

Disodium 1,4-butanedioate hexahydrate;

Butanedioic acid disodium salt hexahydrate CAS RN®: 6106-21-4.

DEFINITION

Sodium Succinate, when dried at 120° for 2 h, contains NLT 98.0% and NMT 102.0% of disodium succinate ($C_4H_4Na_2O_4$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197A or 197K.**▲ (CN 1-May-2020) Dry the Anhydrous Sodium Succinate or Sodium Succinate Hexahydrate sample at 120° for 2 h before use.

• **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. Sodium**

Analysis: Proceed as directed in *Identification Tests—General ⟨191⟩, Sodium*.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Solution A: Dissolve 6.8 g of monobasic potassium phosphate in 2 L of water. Adjust with phosphoric acid to a pH of 2.3. Pass under vacuum through an HNWP (nylon hydrophilic) membrane filter of 0.45-µm pore size. This is a 25 mM potassium phosphate buffer with a pH of 2.3.

Mobile phase: Add 100 mL of methanol to 1900 mL of *Solution A* and mix well. Sonicate for 30 min and cool to room temperature.

Diluent: Add 10 mL of phosphoric acid to 1 L of water and mix well. This is a 1% phosphoric acid solution.

System suitability solution: 3.0 mg/mL of USP Anhydrous Sodium Succinate RS and 2.2 µg/mL of USP Fumaric Acid RS in *Diluent*

Standard solution: 3.0 mg/mL of USP Anhydrous Sodium Succinate RS in *Diluent*

Sample solution: 3.0 mg/mL of Anhydrous Sodium Succinate or Sodium Succinate Hexahydrate in *Diluent*. Dry Anhydrous Sodium Succinate or Sodium Succinate Hexahydrate at 120° for 2 h before use.

Chromatographic system

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

Mode: LC

Detector: UV 204 nm

Column: 4.6-mm × 15-cm; 3-µm packing L1

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

Run time: 10 min

System suitability

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

[NOTE—The relative retention times for succinic acid and fumaric acid are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between succinic acid and fumaric acid, *System suitability solution*

Tailing factor: 0.8–2.0, *Standard solution*

Relative standard deviation: NMT 0.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sodium succinate ($C_4H_4Na_2O_4$) in the portion of sample taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Anhydrous Sodium Succinate or Sodium Succinate Hexahydrate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• **LIMIT OF SODIUM ACETATE, SODIUM MALEATE, AND SODIUM FUMARATE**

Solution A, Mobile phase, Diluent, and **Chromatographic system:** Proceed as directed in the *Assay*.

Acetic acid stock solution: Transfer 37.5 mg of USP Glacial Acetic Acid RS to a 25-mL volumetric flask that contains 10 mL of *Diluent*. Dissolve and dilute with *Diluent* to volume. Transfer 1.0 mL of this solution to a 10-mL volumetric flask and dilute with *Diluent* to volume. This solution is equivalent to 200 µg/mL of sodium acetate in *Diluent*.

Maleic acid stock solution: Transfer 36.5 mg of USP Maleic Acid RS to a 50-mL volumetric flask. Dissolve and dilute with *Diluent* to volume. Transfer 1.0 mL of this solution to a 10-mL volumetric flask and dilute with *Diluent* to volume. This solution is equivalent to 100 µg/mL of sodium maleate in *Diluent*.

Fumaric acid stock solution: Transfer 36.5 mg of USP Fumaric Acid RS to a 50-mL volumetric flask. Dissolve and dilute with *Diluent* to volume. Transfer 1.0 mL of this solution to a 10-mL volumetric flask and dilute with *Diluent* to volume. This solution is equivalent to 100 µg/mL of sodium fumarate in *Diluent*.

System suitability solution: 10 mg/mL of USP Anhydrous Sodium Succinate RS, 15 µg/mL of USP Glacial Acetic Acid RS, and 7.3 µg/mL each of USP Maleic Acid RS and USP Fumaric Acid RS in *Diluent*

Standard solution: Transfer 1 mL each of *Acetic acid stock solution*, *Maleic acid stock solution*, and *Fumaric acid stock solution* to a 10-mL volumetric flask and dilute with *Diluent* to volume.

Sample solution: 10 mg/mL of Anhydrous Sodium Succinate or Sodium Succinate Hexahydrate in *Diluent*

System suitability

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

[NOTE—The relative retention times for acetic acid, maleic acid, succinic acid, and fumaric acid are 0.7, 0.8, 1.0, and 1.2, respectively.]

Suitability requirements

Resolution: NLT 1.5 between acetic acid and maleic acid; NLT 2.0 between succinic acid and fumaric acid, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Based on the *Standard solution*, identify the peaks of acetic acid, maleic acid, and fumaric acid. Compare peak areas of acetic acid, maleic acid, and fumaric acid in the *Standard solution* and the *Sample solution*.

Acceptance criteria

Sodium acetate: The peak area of acetic acid in the *Sample solution* is NMT the peak area of acetic acid in the *Standard solution*, corresponding to NMT 0.2% of sodium acetate in Sodium Succinate.

Sodium maleate: The peak area of maleic acid in the *Sample solution* is NMT the peak area of maleic acid in the *Standard solution*, corresponding to NMT 0.1% of sodium maleate in Sodium Succinate.

Sodium fumarate: The peak area of fumaric acid in the *Sample solution* is NMT the peak area of fumaric acid in the *Standard solution*, corresponding to NMT 0.1% of sodium fumarate in Sodium Succinate.

• **Limit of Sulfate**

Standard solution: 0.4 mL of 0.005 mol/L sulfuric acid

Sample solution: Dissolve 1.0 g of Anhydrous Sodium Succinate or Sodium Succinate Hexahydrate in 30 mL of water and neutralize with a diluted hydrochloric acid (1 in 40).

Analysis: Proceed as directed in *Chloride and Sulfate ⟨221⟩, Sulfate*.

Acceptance criteria: NMT 0.019% as SO_4

SPECIFIC TESTS

• **Acidity and Alkalinity**

Sample solution: Dissolve 1.0 g of Anhydrous Sodium Succinate or Sodium Succinate Hexahydrate in carbon dioxide-free water and dilute with water to 20 mL.

Analysis: Proceed as directed in *pH ⟨791⟩*.

Acceptance criteria: 7.0–9.0

• **Loss on Drying ⟨731⟩**

Analysis: Proceed as directed in *Loss on Drying ⟨731⟩*. Dry at 120° for 2 h.

Acceptance criteria

Anhydrous Sodium Succinate: NMT 2.0%

Sodium Succinate Hexahydrate: 37.0%–41.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at room temperature.

• **Labeling:** Label it to state, as part of the official title, anhydrous or hexahydrate for sodium succinate.

• **USP Reference Standards ⟨11⟩**

USP Anhydrous Sodium Succinate RS
USP Fumaric Acid RS
USP Glacial Acetic Acid RS
USP Maleic Acid RS

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

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

Chromatographic Database Information: Chromatographic Database

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