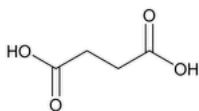


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Succinic Acid

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-succinic-acid-20240531.



$C_4H_6O_4$ 118.09

Butanedioic acid CAS RN®: 110-15-6.

Change to read:

DEFINITION

Succinic Acid contains ▲NLT 98.0% and NMT 102.0%▲ (RB 1-Jun-2024) of succinic acid ($C_4H_6O_4$).

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

• **B. CHROMATOGRAPHIC IDENTITY**

The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• **PROCEDURE**

Diluent: Dissolve 6.8 g of [potassium phosphate, monobasic](#) in 2 L of water. Adjust the pH of the solution to 2.3 with drops of [phosphoric acid](#).

This solution is 25 mM potassium phosphate buffer, pH 2.3.

Mobile phase: [Methanol](#) and *Diluent* (8:92)

System suitability solution: 1.0 mg/mL of [USP Succinic Acid RS](#) and 0.003 mg/mL of [USP Fumaric Acid RS](#) in *Diluent*

Standard solution: 1.0 mg/mL of [USP Succinic Acid RS](#) in *Diluent*

Sample solution: 1.0 mg/mL of Succinic Acid in *Diluent*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 204 nm

Column: 4.6-mm × 15-cm; 3-μm packing [L1](#)

Flow rate: 1.0 mL/min

Injection volume: 20 μL

System suitability

Sample: *System suitability 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

Relative standard deviation: NMT 0.5% for the succinic acid peak

Tailing factor: 0.8–2.0

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of succinic acid ($C_4H_6O_4$) in the portion of ▲Succinic Acid▲ (RB 1-Jun-2024) 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 Succinic Acid RS](#) in the *Standard solution* (mg/mL)
- C_u = concentration of Succinic Acid in the *Sample solution* (mg/mL)

Acceptance criteria: ▲98.0%–102.0%▲ (RB 1-Jun-2024)

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.025%

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 185.0°–190.0°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in a well-closed container. No storage requirements specified.
- [USP REFERENCE STANDARDS \(11\)](#)
 - [USP Fumaric Acid RS](#)
 - [USP Succinic Acid RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SUCCINIC ACID	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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