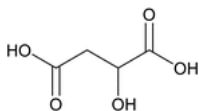


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Malic Acid



$C_4H_6O_5$ 134.09

Hydroxybutanedioic acid, (±)-;

(±)-Malic acid;

(±)-Hydroxysuccinic acid CAS RN®: 617-48-1.

DEFINITION

Malic Acid contains NLT 99.0% and NMT 100.5% of $C_4H_6O_5$.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS 〈197〉, Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020) : On undried sample

ASSAY

• PROCEDURE

Sample: 2 g

Titrimetric system

(See [Titrimetry 〈541〉](#).)

Mode: Direct titration

Titrant: 1 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 40 mL of recently boiled and cooled water. Add phenolphthalein TS, and titrate to the first appearance of a faint pink color that persists for NLT 30 s. Perform a blank determination.

Calculate the percentage of malic acid ($C_4H_6O_5$) in the *Sample* taken:

$$\text{Result} = [(V - B) \times N \times F \times 100]/W$$

V = volume of *Titrant* consumed by the *Sample* (mL)

B = volume of *Titrant* consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 67.04 mg/mEq

W = weight of the *Sample* (mg)

Acceptance criteria: 99.0%–100.5%

IMPURITIES

- [RESIDUE ON IGNITION 〈281〉](#): NMT 0.1%

• FUMARIC AND MALEIC ACIDS

Mobile phase: 0.01 N sulfuric acid

System suitability solution: 1 mg/mL of Malic Acid, 10 µg/mL of [USP Fumaric Acid RS](#), and 4 µg/mL of [USP Maleic Acid RS](#) in *Mobile phase*

Standard solution: 5.0 µg/mL of [USP Fumaric Acid RS](#) and 2.0 µg/mL of [USP Maleic Acid RS](#) in *Mobile phase*

Sample solution: 1.0 mg/mL of Malic Acid in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 6.5-mm × 30-cm; packing L17

Column temperature: 37 ± 1°

Flow rate: 0.6 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for maleic acid, malic acid, and fumaric acid are 0.6, 1.0, and 1.5, respectively.]

Suitability requirements

Resolution: NLT 2.5 for the maleic acid and malic acid peaks; NLT 7.0 for the malic acid and fumaric acid peaks

Relative standard deviation: NMT 2.0% for the maleic acid peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of maleic acid and of fumaric acid in the portion of Malic Acid taken:

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

r_U = peak response of maleic acid or fumaric acid from the *Sample solution*

r_S = peak response of maleic acid or fumaric acid from the *Standard solution*

C_S = concentration of [USP Maleic Acid RS](#) or [USP Fumaric Acid RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Malic Acid in the *Sample solution* (mg/mL)

Acceptance criteria

Fumaric acid: NMT 1.0%

Maleic acid: NMT 0.05%

• WATER-INSOLUBLE SUBSTANCES

Sample: 25 g

Analysis: Dissolve the *Sample* in 100 mL of water, filter the solution through a tared filtering crucible, wash the filter with hot water, and dry at 100° to constant weight.

Acceptance criteria: The increase in weight is NMT 25 mg (0.1%).

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **USP REFERENCE STANDARDS (11)**

[USP Fumaric Acid RS](#)

[USP Maleic Acid RS](#)

[USP Malic Acid RS](#)

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

Topic/Question	Contact	Expert Committee
MALIC ACID	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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