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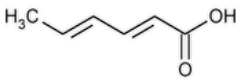
Sorbic Acid

Change to read:



$C_6H_8O_2$ 112.13

2,4-Hexadienoic acid, (*E*,*E*)-; ▲(2*E*,4*E*)-Hexa-2,4-dienoic acid;▲ (NF 1-Dec-2019)

(*E*,*E*)-Sorbic acid ▲▲ (NF 1-Dec-2019) CAS RN®: 110-44-1.

DEFINITION

Change to read:

Sorbic Acid contains NLT ▲98.0%▲ (NF 1-Dec-2019) and NMT ▲102.0%▲ (NF 1-Dec-2019) of sorbic acid ($C_6H_8O_2$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197K▲ (Official 1-May-2020)

• **B.** A 1-in-400,000 solution in isopropyl alcohol exhibits an absorbance maximum at 254 ± 2 nm.

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** 0.1% (v/v) trifluoroacetic acid in water

Solution B: 0.1% (v/v) trifluoroacetic acid in methanol

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
17.0	75	25
18.0	5	95
23.0	5	95
23.1	75	25
30.0	75	25

Diluent: Water and methanol (1:1, v/v)

System suitability solution: Prepare 0.1 mg/mL of USP Sorbic Acid RS in *Diluent* first and then treat the solution with UV irradiation to generate ~1% degradation of sorbic acid (based on area%).[1]

Standard solution: 0.1 mg/mL of USP Sorbic Acid RS in *Diluent*

Sample solution: 0.1 mg/mL of Sorbic Acid in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 264 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing L1

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

Run time: 30 min

System suitability

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

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

Suitability requirements

Resolution: NLT 1.5 between sorbic acid and sorbic acid *trans, cis* isomer, *System suitability solution*

Tailing factor: NMT 2.0, determined from sorbic acid, *Standard solution*

Relative standard deviation: NMT 2.0%, determined from sorbic acid, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sorbic acid in the sample taken:

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

r_U = peak area of sorbic acid from the *Sample solution*

r_S = peak area of sorbic acid from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

Table 2

Name	Relative Retention Time
Sorbic acid *cis, cis* isomer[a]	0.83
Sorbic acid *cis, trans* isomer[b]	0.89
Sorbic acid *trans, cis* isomer[c]	0.92
Sorbic acid	1.0

[a] (*Z*,*Z*)-Sorbic acid.

[b] (*Z*,*E*)-Sorbic acid.

[c] (*E*,*Z*)-Sorbic acid.

[NOTE—Sorbic acid *cis, trans* isomer and sorbic acid *trans, cis* isomer might co-elute in some columns, which has no effect on assay analysis.]▲ (NF 1-Dec-2019)

IMPURITIES

Add the following:

▲• **Limit of Aldehyde**

Decolorized fuchsin solution: Dissolve 0.1 g of basic fuchsin in 60 mL of water. Add a solution containing 1 g of anhydrous sodium sulfite in 10 mL of water. Slowly and with continuous shaking add 2 mL of hydrochloric acid. Dilute with water to 100 mL. Allow to stand protected from light for at least 12 h, decolorize with activated charcoal and filter. If the solution becomes cloudy, filter before use. If on standing the solution becomes violet, decolorize again by adding activated charcoal.

Test for sensitivity: To 1.0 mL of the *Decolorized fuchsin solution* add 1.0 mL of water and 1.0 mL of alcohol, aldehyde-free. Add 0.2 mL of a solution containing 0.1 g/L of formaldehyde (CH_2O). A pale-pink color develops within 5 min.

Storage of *Decolorized fuchsin solution***:** Protected from light

Acetaldehyde standard solution: 100 µg/mL of acetaldehyde (C_2H_4O). Dissolve 1.0 g of acetaldehyde in 2-propanol and dilute with the same solvent to 100.0 mL. Dilute 5.0 mL of the solution with 2-propanol to 500.0 mL. Prepare immediately before use.

Standard solution: Add 1 mL of *Decolorized fuchsin solution* to a mixture of 1.5 mL of *Acetaldehyde standard solution*, 4 mL of 2-propanol, and 4.5 mL of water.

Sample solution: Dissolve 1.0 g of the sample in a mixture of 30 mL of water and 50 mL of 2-propanol, adjust with 0.1 N hydrochloric acid or 0.1 N sodium hydroxide to a pH of 4 and dilute with water to 100 mL.

Analysis: To 10 mL of the *Sample solution* add 1 mL of *Decolorized fuchsin solution* and allow to stand for 30 min. Any color in the solution is not more intense than that in the *Standard solution* prepared at the same time.

Acceptance criteria: NMT 0.15%, as acetaldehyde (C_2H_4O)▲ (NF 1-Dec-2019)

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

SPECIFIC TESTS

• **Melting Range or Temperature ⟨741⟩:** 132°–135°

• **Water Determination ⟨921⟩, *Method I*:** NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, protected from light, and avoid exposure to excessive heat.

• **USP Reference Standards ⟨11⟩**
USP Sorbic Acid RS

[1] UV irradiation conditions of wavelengths of 254, 300, and 365 nm at 18 Watts for 2 h have been used for the solution. Other equivalent UV conditions are also suitable as long as ~1% degradation of sorbic acid (based on area%) can be achieved after the irradiation. Quartz glassware is preferred.

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

Topic/Question	Contact	Expert Committee
SORBIC 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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