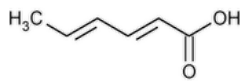


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Sorbic Acid

Change to read:



$C_6H_8O_2$ 112.13
2,4-Hexadienoic acid, (E,E)-; ▲(2E,4E)-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 <i>cis, cis</i> isomer ^a	0.83
Sorbic acid <i>cis, trans</i> isomer ^b	0.89
Sorbic acid <i>trans, cis</i> 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