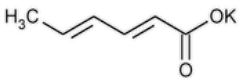
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Nov-2020
Document Type: NF Monographs
DocId: GUID-C8AFACAF-0D82-45A5-BC8D-58739745E9CE_4_en-US
DOI: https://doi.org/10.31003/USPNF_M68040_04_01
DOI Ref: eh3w2

Potassium Sorbate

Change to read:



$C_6H_7KO_2$ 150.22

2,4-Hexadienoic acid, (*E*,*E*)-, potassium salt;

▲Potassium (2*E*,4*E*)-hexa-2,4-dienoate;▲ (NF 1-May-2020)

Potassium (*E*,*E*)-sorbate▲▲ (NF 1-May-2020) CAS RN®: 590-00-1; .24634-61-5.

DEFINITION

Change to read:

Potassium Sorbate contains NLT 98.0% and NMT ▲102.0%▲ (NF 1-May-2020) of potassium sorbate ($C_6H_7KO_2$), calculated on the dried basis.

IDENTIFICATION

• **A. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Potassium***

Sample: Dissolve 1 g of Potassium Sorbate in 10 mL of water.

Acceptance criteria: Meets the requirements

Change to read:

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

ASSAY

Delete the following:

▲• **Procedure**

Sample: 300 mg of Potassium Sorbate

Blank: 40 mL of glacial acetic acid

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 40 mL of glacial acetic acid, warming, if necessary, to dissolve the solution. Cool to room temperature, and add 1 drop of crystal violet TS. Titrate with *Titrant* to a blue-green endpoint. Perform a blank determination.

Calculate the percentage of potassium sorbate ($C_6H_7KO_2$) in the *Sample* taken:

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

V_S = *Titrant* consumed by the *Sample* (mL)

V_B = *Titrant* consumed by the *Blank* (mL)

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

F = equivalency factor, 150.2 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 98.0%–101.0% on the dried basis▲ (NF 1-May-2020)

Add the following:

▲• **Procedure 1: Content of Potassium Sorbate**

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 Potassium Sorbate RS in *Diluent* first and then treat the solution with UV irradiation to generate ~1% degradation of potassium sorbate (based on area%).[1]

Standard solution: 0.1 mg/mL of USP Potassium Sorbate RS in *Diluent*

Sample solution: 0.1 mg/mL of Potassium Sorbate 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 potassium sorbate and potassium sorbate *trans, cis* isomer, *System suitability solution*

Tailing factor: NMT 2.0, determined from potassium sorbate, *Standard solution*

Relative standard deviation: NMT 2.0%, determined from potassium sorbate, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of potassium sorbate in the sample taken:

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

r_U = peak area of potassium sorbate from the *Sample solution*

r_S = peak area of potassium sorbate from the *Standard solution*

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

C_U = concentration of Potassium Sorbate in the *Sample solution* (mg/mL)

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

Table 2

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

[a] Potassium (*Z*,*Z*)-sorbate.

[b] Potassium (*Z*,*E*)-sorbate.

[c] Potassium (*E*,*Z*)-sorbate.

[NOTE—Potassium sorbate *cis, trans* isomer and potassium sorbate *trans, cis* isomer might co-elute in some columns, which has no effects on assay analysis. All the four isomers are in their corresponding sorbic acid forms in the HPLC column because of the acidic mobile phase condition.]▲ (NF 1-MAY-2020)

Add the following:

▲• **Procedure 2: Content of Potassium**

Diluent: 1% hydrochloric acid solution

Sodium chloride solution: 0.2 g/mL of sodium chloride in *Diluent*

Blank solution: 4 mg/mL of sodium chloride from *Sodium chloride solution* in *Diluent*

Standard stock solution: 57.21 µg/mL of potassium chloride, previously dried at 105° for 2 h, in water. This solution contains 30 µg/mL of potassium.

Standard solutions: Transfer 2.0-, 4.0-, and 6.0-mL portions of the *Standard stock solution* to separate 100-mL volumetric flasks. To each flask add 2.0 mL of the *Sodium chloride solution*. Dilute the content of each flask with *Diluent* to volume and mix to obtain solutions with known concentrations of 0.6, 1.2, and 1.8 µg/mL of potassium.

Sample stock solution: 0.46 mg/mL of Potassium Sorbate in water

Sample solution: Transfer 1.0 mL of the *Sample stock solution* to a 100-mL volumetric flask. Add 2.0 mL of the *Sodium chloride solution* and dilute with *Diluent* to volume. The concentration of this solution is 4.6 µg/mL of Potassium Sorbate.

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 766.5 nm (potassium emission line)

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Standard curve

Samples: *Standard solutions*

Plot: Absorbance values versus their corresponding concentrations (µg/mL) of potassium. The correlation coefficient is NLT 0.995.

Analysis

Sample: *Sample solution*

From the *Standard curve*, determine the concentration of potassium in the *Sample solution*.

Calculate the percentage of potassium in the portion of Potassium Sorbate taken:

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

C_S = concentration of potassium in the *Sample solution* from the *Standard curve* (µg/mL)

C_U = concentration of Potassium Sorbate in the *Sample solution* (µg/mL)

Acceptance criteria: 24.5%–27.6%▲ (NF 1-May-2020)

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 *Decolorized fuchsin solution* add 1.0 mL of water and 0.1 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: 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 1 N hydrochloric acid 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-May-2020)

SPECIFIC TESTS

• **Acidity or Alkalinity**

Sample solution: 1.1 g of Potassium Sorbate in 20 mL of water

Analysis: Add phenolphthalein TS to the *Sample solution*.

Acceptance criteria: If the solution is colorless, titrate with 0.10 N sodium hydroxide to a pink color that persists for 15 s: NMT 1.1 mL of 0.10 N sodium hydroxide is required. If the solution is pink in color, titrate with 0.10 N hydrochloric acid to discharge the pink color: NMT 0.80 mL of 0.10 N hydrochloric acid is required.

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

Add the following:

▲• **USP Reference Standards ⟨11⟩**

USP Potassium Sorbate RS▲ (NF 1-May-2020)

[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 potassium sorbate (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
POTASSIUM SORBATE	Documentary Standards Support	SE2020 Simple Excipients

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(2)

Current DocID: GUID-C8AFACAF-0D82-45A5-BC8D-58739745E9CE_4_en-US

DOI: https://doi.org/10.31003/USPNF_M68040_04_01

DOI ref: eh3w2