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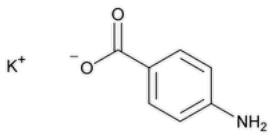
Aminobenzoate Potassium



$C_7H_6KNO_2$ 175.23

Benzoic acid, 4-amino-, potassium salt;

Potassium 4-aminobenzoate CAS RN®: 138-84-1; UNII: 41KZS5432U.

DEFINITION

Aminobenzoate Potassium contains NLT 98.0% and NMT 102.0% of aminobenzoate potassium ($C_7H_6KNO_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

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

• **C.**

Sample solution: 10 mg/mL of Aminobenzoate Potassium in water

Acceptance criteria: The *Sample solution* imparts a violet color to a nonluminous flame. Since the presence of small quantities of sodium masks the color, screen out the yellow color produced by sodium by viewing through a blue filter that blocks emission at 589 nm (sodium) but is transparent to emission at 404 nm (potassium). [Note—Traditionally, cobalt glass has been used, but other suitable filters are commercially available.]

ASSAY

• **Procedure**

Solution A: 1.5% acetic acid, prepared by mixing 690 mL of water with 10 mL of glacial acetic acid and passing through a suitable filter of 0.45-µm pore size

Mobile phase: Methanol and *Solution A* (15:85)

Standard solution: 0.1 mg/mL of USP Aminobenzoate Potassium RS in *Mobile phase*. Sonicate to dissolve.

Sample solution: 0.1 mg/mL of Aminobenzoate Potassium in *Mobile phase*. Sonicate to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.0-mm × 15-cm; 3.5-µm packing L11

Flow rate: 0.35 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aminobenzoate potassium ($C_7H_6KNO_2$) in the portion of Aminobenzoate Potassium 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 Aminobenzoate Potassium RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

Delete the following:

▲• **Heavy Metals** ⟨231⟩, *Method II*: NMT 0.002% ▲ (Official 1-Jan-2018)

Change to read:

• **Limit of Aniline and *p*-Toluidine**

Diluent: Methylene chloride

Standard stock solution: 0.1 mg/mL each of USP Aniline RS and USP p-Toluidine RS in *Diluent*

Standard solution: 1 µg/mL each of USP Aniline RS and USP p-Toluidine RS in *Diluent* from *Standard stock solution*

Sample solution: 100 mg/mL of Aminobenzoate Potassium in *Diluent* prepared as follows. Add an appropriate quantity of Aminobenzoate Potassium to a suitable volumetric flask and dilute with *Diluent* to volume. Agitate for 10 min on a shaker and centrifuge at 3000 rpm for 5 min. Use the supernatant.

Chromatographic system

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

Mode: GC

Detectors

Flame ionization: 300°

Hydrogen: 40 mL/min

Air: 400 mL/min

Column: 30-m × 0.32-mm fused silica capillary; coated with 0.5-µm film of phase G27

Temperatures

Injection port: 280°

Detector: 300°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
130	—	130	4
130	20	180	5

Carrier gas: Helium

Flow rate: 1.0 mL/min

Injection volume: 2 µL

Injection type: Split ratio, 1:10

System suitability

Sample: *Standard solution*

[Note—The relative retention times of aniline and *p*-toluidine are ▲0.8 and 1.0,▲ (ERR 1-Sep-2018) respectively.]

Suitability requirements

Resolution: NLT 7.0 between aniline and *p*-toluidine

Tailing factor: NMT 1.5 for aniline and *p*-toluidine

Relative standard deviation: NMT 6.0% for aniline and *p*-toluidine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of *p*-toluidine or aniline in the portion of Aminobenzoate Potassium taken:

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

r_U = peak response of *p*-toluidine or aniline from the *Sample solution*

r_S = peak response of *p*-toluidine or aniline from the *Standard solution*

C_S = concentration of the corresponding USP Reference Standard in the *Standard solution* (mg/mL)

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

Acceptance criteria

Aniline: NMT 10 ppm

***p*-Toluidine:** NMT 20 ppm

- **Organic Impurities**

Solution A: 1.5% acetic acid, prepared by mixing 690 mL of water with 10 mL of glacial acetic acid

Solution B: Methanol

Mobile phase: See *Table 2*.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0.0	85	15
4.0	85	15
4.1	45	55
10.0	45	55
10.1	85	15
13	85	15

Diluent: Methanol and water (85:15)

System suitability solution: 1 mg/mL of USP Aminobenzoate Potassium RS, 0.01 mg/mL of USP 4-Nitrobenzoic Acid RS, and 0.01 mg/mL of USP Benzocaine RS in *Diluent* prepared as follows. Transfer 1 mL each of 0.1 mg/mL of USP 4-Nitrobenzoic Acid RS in methanol and 0.1 mg/mL of USP Benzocaine RS in *Diluent* to a 10-mL volumetric flask containing the appropriate amount of USP Aminobenzoate Potassium RS, and dilute with *Diluent* to volume.

Standard solution: 1 µg/mL each of USP Aminobenzoate Potassium RS, USP 4-Nitrobenzoic Acid RS, and USP Benzocaine RS in *Diluent*

Sample solution: 1 mg/mL of Aminobenzoate Potassium in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.0-mm × 15-cm; 3.5-µm packing L11

Flow rate: 0.4 mL/min

Injection volume: 5 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between benzocaine and 4-nitrobenzoic acid, *System suitability solution*

Relative standard deviation: NMT 3% for the aminobenzoate potassium, 4-nitrobenzoic acid, and benzocaine peaks, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 4-nitrobenzoic acid or benzocaine in the portion of Aminobenzoate Potassium taken:

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

r_U = peak response of 4-nitrobenzoic acid or benzocaine from the *Sample solution*

r_S = peak response of 4-nitrobenzoic acid or benzocaine from the *Standard solution*

C_S = concentration of USP 4-Nitrobenzoic Acid RS or USP Benzocaine RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Aminobenzoate Potassium taken:

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

r_U = peak response of any unspecified impurity from the *Sample solution*

r_S = peak response of aminobenzoate from the *Standard solution*

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

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

Acceptance criteria: See *Table 3*.

Table 3

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Aminobenzoic acid	1.0	—
Benzocaine	2.0	0.2
4-Nitrobenzoic acid	2.1	0.2
Any individual unspecified impurity	—	0.10

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample solution: 50 mg/mL of Aminobenzoate Potassium in water

  Acceptance criteria: 8.0–9.0

- **Loss on Drying** ⟨731⟩

  Analysis: Dry at 105° for 2 h.

  Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

USP Aminobenzoate Potassium RS

USP Aniline RS

Aniline.

C_6H_7N 93.13

USP Benzocaine RS

USP 4-Nitrobenzoic Acid RS

4-Nitrobenzoic acid.

$C_7H_5NO_4$ 167.12

USP p-Toluidine RS

4-Methylaniline.

C_7H_9N 107.15

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

Topic/Question	Contact	Expert Committee
AMINOBENZOATE POTASSIUM	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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