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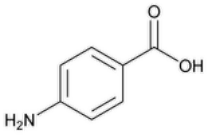
Aminobenzoic Acid



$C_7H_7NO_2$ 137.14

Benzoic acid, 4-amino;

p-Aminobenzoic acid CAS RN®: 150-13-0; UNII: TL2TJE8QTX.

DEFINITION

Aminobenzoic Acid contains NLT 98.0% and NMT 102.0% of aminobenzoic acid ($C_7H_7NO_2$), 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*.

ASSAY

• **Procedure**

Acetic acid solution: Glacial acetic acid and water (1:69)

Mobile phase: Methanol and *Acetic acid solution* (15:85)

Standard solution: 0.1 mg/mL of USP Aminobenzoic Acid RS in *Mobile phase*. Sonicate to aid dissolution.

Sample solution: 0.1 mg/mL of Aminobenzoic Acid in *Mobile phase*. Sonicate to aid dissolution.

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

Sample: *Standard solution*

Suitability requirements

Tailing: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aminobenzoic acid ($C_7H_7NO_2$) in the portion of Aminobenzoic Acid 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 the *Standard solution* (mg/mL)

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

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

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

Solution A: Acetonitrile and methanol (70:80)

Buffer: 1.5 g/L of monobasic potassium phosphate and 2.5 g/L of octanesulfonic acid sodium salt in water. Adjust with phosphoric acid to a pH of 2.2.

Mobile phase: *Solution A* and *Buffer* (20:80)

Standard stock solution: 0.25 mg/mL each of USP Benzocaine RS and 4-nitrobenzoic acid in methanol

Standard solution: 0.5 µg/mL each of USP Benzocaine RS and 4-nitrobenzoic acid in *Mobile phase*, from the *Standard stock solution*

Sample solution: 0.25 mg/mL of Aminobenzoic Acid in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.0-mm × 15-cm; 5-µm packing L7

Flow rate: 1.0 mL/min

Injection volume: 20 µL

Run time: 11 times the retention time of the aminobenzoic acid peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 4-nitrobenzoic acid or any unspecified impurity in the portion of Aminobenzoic Acid taken:

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

r_U = peak response of 4-nitrobenzoic acid or any unspecified impurity from the *Sample solution*

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

C_S = concentration of 4-nitrobenzoic acid in the *Standard solution* (mg/mL)

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

Calculate the percentage of benzocaine in the portion of Aminobenzoic Acid taken:

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

r_U = peak response of benzocaine from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 1*. Disregard any impurity peaks less than 0.02%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Aminobenzoic acid	1.0	—
4-Nitrobenzoic acid	4.0	0.2
Benzocaine	9.0	0.2
Any individual unspecified impurity	—	0.1
Total impurities	—	0.5

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

Diluent: 84 g/L of sodium hydroxide in water

Standard solution: 1.0 µg/mL each of aniline and *p*-toluidine in methylene chloride

Sample solution: Dissolve 1 g of Aminobenzoic Acid in 10.0 mL of *Diluent*, and extract with two quantities each of 10.0 mL of methylene chloride. Combine, and wash with 5 mL of water. Filter through anhydrous sodium sulfate, and wash the filter with methylene chloride.

Evaporate in a water bath at 50°–60° to obtain a volume of about 1–5 mL. Transfer to a 10-mL volumetric flask, and dilute with methylene chloride to volume.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

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

Temperatures

Injection port: 280°

Detector: 300°

Column: See *Table 2*.

Table 2

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
130	0	130	4
130	20	180	5

Carrier gas: Helium

Flow rate: 1.0 mL/min

Injection volume: 2 µL

Split ratio: 1:10

Analysis

Samples: *Standard solution* and *Sample solution*

[Note—The relative retention times for aniline and *p*-toluidine are about 0.8 and 1.0, respectively.]

Calculate, in ppm, the amount of aniline and *p*-toluidine in the portion of Aminobenzoic Acid taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 10^6$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of the corresponding impurity from the *Standard solution*

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

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

Acceptance criteria

Aniline: NMT 10 ppm

***p*-Toluidine:** NMT 10 ppm

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry a sample at 105° for 2 h.

Acceptance criteria: NMT 0.2%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Aminobenzoic Acid RS

USP Benzocaine RS

Benzoic acid, 4-amino-, ethyl ester.

$C_9H_{11}NO_2$ 165.19

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

Topic/Question	Contact	Expert Committee
AMINOBENZOIC ACID	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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