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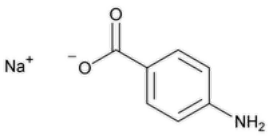
Aminobenzoate Sodium



$C_7H_6NNaO_2$ 159.12

Benzoic acid, 4-amino-, sodium salt;

Sodium 4-aminobenzoate CAS RN®: 555-06-6; UNII: 75UI7QUZ5J.

DEFINITION

Aminobenzoate Sodium contains NLT 98.0% and NMT 102.0% of aminobenzoate sodium ($C_7H_6NNaO_2$), 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.** **Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium*:** A solution (1 in 100) meets the requirements of the flame test.

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 Sodium RS in *Mobile phase*. Sonicate to dissolve.

Sample solution: 0.1 mg/mL of Aminobenzoate Sodium 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 sodium ($C_7H_6NNaO_2$) in the portion of Aminobenzoate Sodium 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 Sodium RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- **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: 1.0 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 Sodium in *Diluent* prepared as follows. Add an appropriate quantity of Aminobenzoate Sodium 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 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 about 4.1 and 5.1 min, 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 Sodium 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 Sodium 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 Sodium 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 Sodium RS, and dilute with *Diluent* to volume.

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

Sample solution: 1 mg/mL of Aminobenzoate Sodium 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 sodium, 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 Sodium 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 Sodium in the *Sample solution* (mg/mL)

Calculate the percentage of any individual unspecified impurity in the portion of Aminobenzoate Sodium 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 Sodium RS in the *Standard solution* (mg/mL)

C_U = concentration of Aminobenzoate Sodium 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

  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 Sodium 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 107.16

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

Topic/Question	Contact	Expert Committee
AMINOBENZOATE SODIUM	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

Most Recently Appeared In:
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