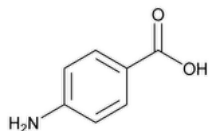


Status: Currently Official on 13-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-59A44EFF-63F2-43C3-A918-3AA72E371584_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M2810_04_01
 DOI Ref: pv8x8

© 2025 USPC
 Do not distribute

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.