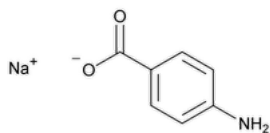


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## Aminobenzoate Sodium



$C_7H_6NNaO_2$  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