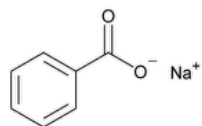


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Sodium Benzoate



$C_7H_5NaO_2$ 144.10

Benzoic acid, sodium salt;

Sodium benzoate CAS RN[®]: 532-32-1.

DEFINITION

Sodium Benzoate contains NLT 99.0% and NMT 101.0% of sodium benzoate ($C_7H_5NaO_2$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
Sample: Undried sample
Acceptance criteria: Meets the requirements
- **B.** [IDENTIFICATION TESTS—GENERAL, Sodium \(191\)](#): Meets the requirements
- **C.** 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

Solution A: Adjust a 20-mM solution of monobasic potassium phosphate with phosphoric acid to a pH of 2.5.

Mobile phase: *Solution A* and acetonitrile (70:30)

Diluent: Water and acetonitrile (50:50)

System suitability solution: 0.1 mg/mL of [USP Salicylic Acid RS](#) and 0.1 mg/mL of [USP Benzoic Acid RS](#) in *Diluent*

Standard solution: 0.1 mg/mL of [USP Benzoic Acid RS](#) in *Diluent*

Sample solution: 0.1 mg/mL of Sodium Benzoate in *Diluent*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Column temperature: 25°

Flow rate: 1.0 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—The relative retention times for benzoic acid and salicylic acid are approximately 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 3.0 between benzoic acid and salicylic acid, *System suitability solution*

Relative standard deviation: NMT 0.5% for benzoic acid, *Standard solution*

Tailing factor: NMT 2.0 for benzoic acid, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sodium benzoate ($C_7H_5NaO_2$) in the portion of Sodium Benzoate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak area of benzoic acid from the *Sample solution*

r_S = peak area of benzoic acid from the *Standard solution*

C_S = concentration of benzoic acid in the *Standard solution*, corrected for purity (mg/mL)

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

M_{r1} = molecular weight of sodium benzoate, 144.10

M_{r2} = molecular weight of benzoic acid, 122.12

Acceptance criteria: 99.0%–101.0% on the anhydrous basis

SPECIFIC TESTS

- [WATER DETERMINATION, Method I \(921\)](#): NMT 1.5%

• ALKALINITY

Sample solution: 2 g in 20 mL of hot water

Analysis: To the *Sample solution* add 2 drops of phenolphthalein TS.

Acceptance criteria: The pink color produced, if any, is discharged by the addition of 0.20 mL of 0.10 N sulfuric acid.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Benzoic Acid RS](#)

[USP Salicylic Acid RS](#)

[USP Sodium Benzoate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SODIUM BENZOATE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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