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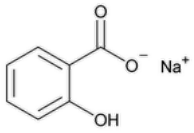
Sodium Salicylate



$C_7H_5NaO_3$ 160.10

Benzoic acid, 2-hydroxy-, monosodium salt;

Monosodium salicylate CAS RN®: 54-21-7; UNII: WIQ1H85SYP.

DEFINITION

Sodium Salicylate contains NLT 98.0% and NMT 102.0% of sodium salicylate ($C_7H_5NaO_3$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.** **Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**
- **B.** **Identification Tests—General, *Sodium* ⟨191⟩**

  Sample solution: 50 mg/mL of Sodium Salicylate in water

  Analysis: Proceed as directed for *Sodium* in the chapter.

  Acceptance criteria: 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**

  Mobile phase: Methanol, trifluoroacetic acid, and water (40:0.1:60)

  Standard solution: 0.04 mg/mL of USP Sodium Salicylate RS in *Mobile phase*

  Sample solution: 0.04 mg/mL of Sodium Salicylate in *Mobile phase*

  Chromatographic system

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

  Mode: LC

  Detector: UV 212 nm

  Column: 2.1-mm × 5-cm; 1.7-µm packing L1

  Column temperature: 30°

  Flow rate: 0.2 mL/min

  Injection volume: 2 µL

  System suitability

  Sample: *Standard solution*

  Suitability requirements

  Tailing factor: 0.8–1.8

  Relative standard deviation: NMT 0.73%

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Calculate the percentage of sodium salicylate ($C_7H_5NaO_3$) in the portion of Sodium Salicylate 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 Sodium Salicylate RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• **Sulfite or Thiosulfate**

Sample solution: 1.0 g of Sodium Salicylate in 20 mL of water

Analysis: Add 1 mL of hydrochloric acid to the *Sample solution*, and filter the liquid.

Acceptance criteria: NMT 0.15 mL of 0.10 N iodine is required to produce a yellow color in the filtrate.

• **Organic Impurities**

Mobile phase: Methanol, trifluoroacetic acid, and water (40:0.1:60)

Standard stock solution: 0.125 mg/mL of USP Sodium Salicylate RS, 0.25 mg/mL of USP Salicylic Acid Related Compound A RS, 0.125 mg/mL of USP Salicylic Acid Related Compound B RS, and 0.05 mg/mL of USP Phenol RS in *Mobile phase*

Standard solution: 1.25 µg/mL of USP Sodium Salicylate RS, 2.5 µg/mL of USP Salicylic Acid Related Compound A RS, 1.25 µg/mL of USP Salicylic Acid Related Compound B RS, and 0.5 µg/mL of USP Phenol RS in *Mobile phase* from *Standard stock solution*

Sample solution: 2.5 mg/mL of Sodium Salicylate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 212 nm

Column: 2.1-mm × 5-cm; 1.7-µm packing L1

Column temperature: 30°

Flow rate: 0.2 mL/min

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between salicylic acid related compound A and phenol; NLT 3.0 between phenol and salicylic acid related compound B

Relative standard deviation: NMT 2% for each peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of salicylic acid related compound A, salicylic acid related compound B, or phenol in the portion of Sodium Salicylate taken:

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

r_U = peak response of salicylic acid related compound A, salicylic acid related compound B, or phenol from the *Sample solution*

r_S = peak response of salicylic acid related compound A, salicylic acid related compound B, or phenol from the *Standard solution*

C_S = concentration of USP Salicylic Acid Related Compound A RS, USP Salicylic Acid Related Compound B RS, or USP Phenol RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other individual impurity in the portion of Sodium Salicylate taken:

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

r_U = peak response of any other individual impurity from the *Sample solution*

r_S = peak response of salicylic acid related compound B from the *Standard solution*

C_S = concentration of USP Salicylic Acid Related Compound B RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid related compound A	0.3	0.1
Phenol	0.4	0.02

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid related compound B	0.6	0.05
Salicylic acid	1.0	—
Any other individual impurity	—	0.05
Total impurities	—	0.2

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 0.5%

ADDITIONAL REQUIREMENTS

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

Change to read:

• **USP Reference Standards ⟨11⟩**

▲USP Phenol RS▲ (ERR 1-Dec-2023)

USP Salicylic Acid Related Compound A RS

4-Hydroxybenzoic acid.

$C_7H_6O_3$ 138.12

USP Salicylic Acid Related Compound B RS

4-Hydroxyisophthalic acid.

$C_8H_6O_5$ 182.13

USP Sodium Salicylate RS

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

Topic/Question	Contact	Expert Committee
SODIUM SALICYLATE	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

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