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Sodium Salicylate Tablets

DEFINITION
Sodium Salicylate Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of sodium salicylate ($C_7H_5NaO_3$).

IDENTIFICATION

- **A.**

  Sample: 50 mg/mL of sodium salicylate in water from powdered Tablets. Filter and use the filtrate.

  Acceptance criteria: The sample imparts an intense yellow color to a nonluminous flame.

- **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**

  Mobile phase: Methanol, trifluoroacetic acid, and water (40:0.1:60). Prepare by adding 1 mL of trifluoroacetic acid to a solution containing 400 mL of methanol and 600 mL of water.

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

  Sample stock solution: Nominally 0.4 mg/mL of sodium salicylate from NLT 20 finely powdered Tablets in *Mobile phase* prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add 60% of the flask volume of *Mobile phase*, and sonicate for 10 min. Allow the solution to cool to room temperature and then dilute with *Mobile phase* to volume.

  Sample solution: Nominally 0.04 mg/mL of sodium salicylate in *Mobile phase* from *Sample stock solution*. Pass through a suitable filter of 0.20-µm pore size, discarding the first 2–3 mL of the filtrate.

  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 1.0%

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Calculate the percentage of the labeled amount of sodium salicylate ($C_7H_5NaO_3$) in the portion of Tablets 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 = nominal concentration of sodium salicylate in the *Sample solution* (mg/mL)

  Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Standard solution: A known concentration of USP Sodium Salicylate RS in *Medium*

Sample solution: Filter portions of the solution under test, and dilute with water, if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 230 nm

Analysis: Determine the amount of sodium salicylate ($C_7H_5NaO_3$) dissolved from UV absorbance of the *Sample solution*, in comparison with that of the *Standard solution*.

Tolerances: NLT 75% (*Q*) of the labeled amount of sodium salicylate ($C_7H_5NaO_3$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Mobile phase: Methanol, trifluoroacetic acid, and water (40:0.1:60). Prepare by adding 1 mL of trifluoroacetic acid to a solution containing 400 mL of methanol and 600 mL of water.

System suitability solution: 0.5 mg/mL of USP Sodium Salicylate RS, 0.5 µg/mL of USP Salicylic Acid Related Compound A RS, 0.5 µg/mL of USP Salicylic Acid Related Compound B RS, and 0.5 µg/mL of USP Phenol RS in *Mobile phase*

Standard solution: 2.5 µg/mL of USP Sodium Salicylate RS in *Mobile phase*

Sample solution: Nominally 2.5 mg/mL of sodium salicylate from NLT 20 finely powdered Tablets in *Mobile phase* prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add 60% of the flask volume of *Mobile phase*, and sonicate for 15 min. Allow the solution to cool to room temperature and then dilute with *Mobile phase* to volume. Centrifuge the solution, and use the supernatant.

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

Samples: *System suitability solution* and *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, *System suitability solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual unspecified impurity in the portion of Tablets taken:

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

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

r_S = peak response of sodium salicylate from the *Standard solution*

C_S = concentration of USP Sodium Salicylate RS in the *Standard solution* (mg/mL)

C_U = nominal 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[a]	0.3	—
Phenol[a]	0.4	—
Salicylic acid related compound B[a]	0.6	—
Salicylic acid	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	1.0

[a] These are process impurities, which are included in the table for identification only. These impurities are controlled in the drug substance. They are not to be reported for the drug product and should not be included in the total impurities.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

USP Phenol RS

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 TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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