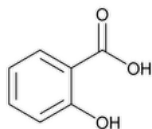


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Salicylic Acid



$C_7H_6O_3$ 138.12
Benzoic acid, 2-hydroxy-;
Salicylic acid CAS RN[®]: 69-72-7; UNII: O414PZ4LPZ.

DEFINITION

Salicylic Acid contains NLT 98.0% and NMT 102.0% of salicylic acid ($C_7H_6O_3$), 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

Mobile phase: Methanol, glacial acetic acid, and water (40:1:60), prepared by adding 10 mL of glacial acetic acid to a solution containing 400 mL of methanol and 600 mL of water

Standard solution: 0.5 mg/mL of [USP Salicylic Acid RS](#) in *Mobile phase*. Sonicate to dissolve as needed.

Sample solution: 0.5 mg/mL of Salicylic Acid in *Mobile phase*. Sonicate to dissolve as needed.

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 10-cm; 5-μm packing L1

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of salicylic acid ($C_7H_6O_3$) in the portion of Salicylic 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 [USP Salicylic Acid RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Salicylic Acid in the *Sample solution* (mg/mL)

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

IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.05%

• **CHLORIDE AND SULFATE, Chloride(221).**

Sample: 1.5 g

Analysis: Heat the *Sample* with 75 mL of water until it is dissolved. Cool, add water to restore the original volume, and filter.

Acceptance criteria: A 25-mL portion of the filtrate shows no more chloride than corresponds to 0.10 mL of 0.020 N hydrochloric acid. (0.014%)

• **CHLORIDE AND SULFATE, Sulfate(221).**

Sample solution: 1.0 g in alcohol and water (1:1)

Acceptance criteria: No more sulfate than corresponds to 0.2 mL of 0.020 N sulfuric acid (0.02%)

• **ORGANIC IMPURITIES**

Mobile phase: Prepare as directed in the Assay.

Diluent: Methanol, glacial acetic acid, and water (70:4:30)

Standard solution: 0.5 mg/mL of [USP Salicylic Acid RS](#), 0.05 mg/mL of [USP Salicylic Acid Related Compound A RS](#), 0.025 mg/mL of [USP Salicylic Acid Related Compound B RS](#), and 0.01 mg/mL of [USP Phenol RS](#) in *Diluent*

Peak identification solution: 0.01 mg/mL of [USP Phenol RS](#) in *Diluent*

Sample solution: 50 mg/mL of Salicylic Acid in *Diluent*. Sonicate until completely dissolved.

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 0.5 mL/min

Injection volume: 2 µL

System suitability

Samples: *Standard solution* and *Peak identification solution*

Suitability requirements

[NOTE—Identify the elution order of phenol by comparing with the *Peak identification solution*.]

Resolution: NLT 2.0 between any two peaks, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of salicylic acid related compound A, salicylic acid related compound B, and phenol in the portion of Salicylic Acid 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 Salicylic Acid in the *Sample solution* (mg/mL)

Calculate the percentage of any other individual impurity in the portion of Salicylic Acid 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 Salicylic Acid in the *Sample solution* (mg/mL)

Acceptance criteria: See [Table 1](#). [NOTE—The elution order for salicylic acid related compound B and phenol may switch.]

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid related compound A	0.35	0.1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid related compound B	0.45	0.05
Phenol	0.50	0.02
Salicylic acid	1.0	—
Any other individual impurity	—	0.05
Total impurities	—	0.2

SPECIFIC TESTS• [LOSS ON DRYING \(731\)](#)**Analysis:** Dry over silica gel for 3 h.**Acceptance criteria:** NMT 0.5%**ADDITIONAL REQUIREMENTS**• **PACKAGING AND STORAGE:** Preserve in well-closed containers.• [USP REFERENCE STANDARDS \(11\)](#)[USP Phenol RS](#)[USP Salicylic Acid RS](#)[USP Salicylic Acid Related Compound A RS](#)

4-Hydroxybenzoic acid.

C₇H₆O₃ 138.12[USP Salicylic Acid Related Compound B RS](#)

4-Hydroxyisophthalic acid.

C₈H₆O₅ 182.13**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SALICYLIC ACID	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)**Most Recently Appeared In:**

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