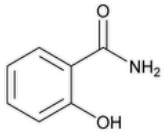
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-498EB196-0C39-4166-993D-243C6CF635BD_4_en-US
DOI: https://doi.org/10.31003/USPNF_M74280_04_01
DOI Ref: 53g01

Salicylamide



$C_7H_7NO_2$ 137.14

Benzamide, 2-hydroxy-;

2-Hydroxybenzamide CAS RN®: 65-45-2; UNII: EM8BM710ZC.

DEFINITION

Salicylamide contains NLT 98.0% and NMT 102.0% of salicylamide ($C_7H_7NO_2$), calculated on the anhydrous 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 *Assay*.

ASSAY

• **Procedure**

Solution A: 0.1% Formic acid in water

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	92	8
6.0	55	45
6.5	5	95
8.0	5	95
8.01	92	8
12.0	92	8

Diluent: Acetonitrile and water (50:50)

System suitability solution: 1.0 mg/mL of USP Salicylamide RS and 0.001 mg/mL of USP Salicylic Acid Related Compound B RS in *Diluent*

Standard solution: 0.2 mg/mL of USP Salicylamide RS in *Diluent*

Sample solution: 0.2 mg/mL of Salicylamide in *Diluent*. Pass through a suitable filter of 0.2-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 300 nm

Column: 2.1-mm × 10-cm; 1.8-µm packing L1

Column temperature: 35°

Flow rate: 0.3 mL/min

Injection volume: 1 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between salicylic acid related compound B and salicylamide, *System suitability solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of salicylamide ($C_7H_7NO_2$) in the portion of Salicylamide 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 Salicylamide RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.1%
- **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.001 mg/mL each of USP Salicylamide RS and USP Salicylic Acid RS in *Diluent*

Sample solution: 1.0 mg/mL of Salicylamide in *Diluent*. Pass through a suitable filter of 0.2-µm pore size.

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between salicylic acid related compound B and salicylamide, *System suitability solution*

Relative standard deviation: NMT 2.8%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of salicylic acid in the portion of Salicylamide taken:

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

r_U = peak response of the salicylic acid peak from the *Sample solution*

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

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

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

Calculate the percentage of each unspecified impurity in the portion of Salicylamide taken:

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

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

r_S = peak response of salicylamide from the *Standard solution*

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

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

Acceptance criteria: See *Table 2*. Disregard any impurity peak less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid related compound B[a]	0.93	—
Salicylamide	1.00	—
Salicylic acid	1.33	0.1
Individual unspecified impurity	—	0.10
Total impurities	—	1

[a] For identification only.

SPECIFIC TESTS

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

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Salicylamide RS

USP Salicylic Acid RS

USP Salicylic Acid Related Compound B RS

4-Hydroxyisophthalic acid.

$C_8H_6O_5$ 182.13

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

Topic/Question	Contact	Expert Committee
SALICYLAMIDE	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-498EB196-0C39-4166-993D-243C6CF635BD_4_en-US

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