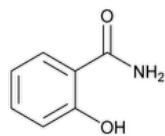


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Salicylamide



$C_7H_7NO_2$ 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)