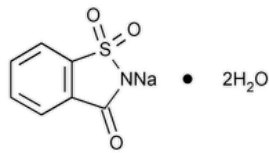


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Saccharin Sodium



$C_7H_4NNaO_3S \cdot 2H_2O$ 241.20
 $C_7H_4NNaO_3S$ 205.17
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt, dihydrate;
1,2-Benzisothiazolin-3-one 1,1-dioxide sodium salt dihydrate CAS RN®: 6155-57-3.
Anhydrous CAS RN®: 128-44-9.

DEFINITION
Saccharin Sodium contains NLT 98.0% and NMT 102.0% of saccharin sodium ($C_7H_4NNaO_3S$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
Sample: Dry at 105° to constant weight.
Acceptance criteria: Meets the requirements
- **B.**
Sample solution: 100 mg/mL
Potassium pyroantimonate solution: Dissolve 2 g of [potassium pyroantimonate](#) in 95 mL of hot water. Cool quickly, and add 50 mL of a [potassium hydroxide](#) solution (50 mg/mL) and 1 mL of [sodium hydroxide](#) solution (8.5 in 100). Allow to stand for 24 h, filter, and dilute with water to 150 mL.
Analysis: To 10 mL of the *Sample solution* add 2 mL of 15% [potassium carbonate](#), and heat to boiling. No precipitate is formed. Add 4 mL of *Potassium pyroantimonate solution*, and heat to boiling. Allow to cool in ice water and, if necessary, rub the inside of the test tube with a glass rod.
Acceptance criteria: A dense precipitate is formed.
- **C.** Sodium salts impart an intense yellow color to a nonluminous flame.

ASSAY

- **PROCEDURE**
Solution A: 50 mM [dibasic potassium phosphate](#) (K_2HPO_4) buffer in 0.1% (v/v) [phosphoric acid](#) solution
Solution B: Methanol
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
7.0	90	10

Time (min)	Solution A (%)	Solution B (%)
8.0	5	95
10.0	5	95
10.1	90	10
15.0	90	10

Diluent: Methanol and water (50:50 v/v)

System suitability solution: 0.1 mg/mL of [phthalic anhydride](#) and 0.1 mg/mL of [USP Saccharin Sodium RS](#) in *Diluent*

Standard solution: 0.1 mg/mL of [USP Saccharin Sodium RS](#) in *Diluent*

Sample solution: 0.1 mg/mL of Saccharin Sodium in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

Column temperature: 20 ± 5°

Flow rate: 1.0 mL/min

Injection volume: 10 μL

Run time: 15 min

System suitability

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

[NOTE—The retention times for phthalic anhydride and saccharin sodium are about 6.3 and 7.3 min, respectively. Phthalic anhydride is a potential impurity.]

Suitability requirements

Resolution: NLT 1.5 between the phthalic anhydride and saccharin sodium peaks, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 0.73% for five replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of saccharin sodium in the portion of Saccharin Sodium taken:

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

r_U = peak area of saccharin sodium from the *Sample solution*

r_S = peak area of saccharin sodium from the *Standard solution*

C_S = concentration of [USP Saccharin Sodium RS](#) in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• LIMIT OF TOLUENESULFONAMIDES

Internal standard solution: 0.25 mg/mL of caffeine in [methylene chloride](#)

Standard stock solution: 20.0 μg/mL of [USP o-Toluenesulfonamide RS](#) and 20.0 μg/mL of [USP p-Toluenesulfonamide RS](#) in [methylene chloride](#)

Standard solution: Evaporate 5.0 mL of *Standard stock solution* to dryness in a stream of nitrogen. Dissolve the residue in 1.0 mL of the *Internal standard solution*.

Sample stock solution: 200 mg/mL in water. If necessary, adjust with [1 N sodium hydroxide](#) or [1 N hydrochloric acid](#) to a pH of 7–8 before final dilution.