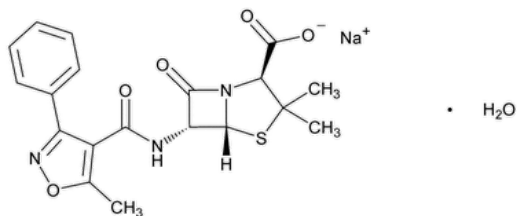


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-92660150-5700-4536-9386-DC9B36F6C024_4_en-US
DOI: https://doi.org/10.31003/USPNF_M59030_04_01
DOI Ref: 08sp9

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Oxacillin Sodium



$C_{19}H_{18}N_3NaO_5S \cdot H_2O$ 441.43
4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-6-[[[(5-methyl-3-phenyl-4-isoxazolyl)-carbonyl]amino]-7-oxo-, monosodium salt, monohydrate, [2S-(2 α ,5 α ,6 β)];
Monosodium (2S,5R,6R)-3,3-dimethyl-6-(5-methyl-3-phenyl-4-isoxazolecarboxamido)-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate CAS RN®: 7240-38-2; UNII: G0V6C994Q5.
Anhydrous
 $C_{19}H_{18}N_3NaO_5S$ 423.43 CAS RN®: 1173-88-2; UNII: 4TWD2995UP.

DEFINITION
Oxacillin Sodium contains the equivalent of NLT 815 µg/mg and NMT 950 µg/mg of oxacillin ($C_{19}H_{19}N_3O_5S$).

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.
- **C.** **IDENTIFICATION TESTS—GENERAL (191), Sodium:** Meets the requirements

ASSAY

• **PROCEDURE**

Protect solutions containing oxacillin from light.
Solution A: 1.18 g/L of sodium 1-hexanesulfonate monohydrate and 0.8 mL/L of ammonium hydroxide in water, adjusted with phosphoric acid to a pH of 2.8–3.2
Solution B: Acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
20	30	70

Return to the original conditions and re-equilibrate the system.

Diluent: Acetonitrile and water (15:85)

System suitability stock solution: 0.1 mg/mL of [USP Oxacillin Related Compound C RS](#) in *Diluent*. Sonicate as needed to dissolve.

System suitability solution: 0.01 mg/mL of [USP Oxacillin Related Compound C RS](#) from *System suitability stock solution* and *Diluent*.
[Oxacillin Sodium RS](#) in *Diluent*. Store this solution at 4°.

Standard solution: 1 mg/mL of [USP Oxacillin Sodium RS](#) in *Diluent*. Sonicate as needed to dissolve. Store this solution at 4°.

Sample solution: 1 mg/mL of Oxacillin Sodium in *Diluent*. Sonicate as needed to dissolve. Store this solution at 4°.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Temperatures

Column: 40°

Autosampler: 4°

Flow rate: 1.5 mL/min

Injection volume: 2 µL

System suitability

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

[NOTE—The relative retention times for oxacillin related compound C and oxacillin are about 0.96 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between oxacillin related compound C and oxacillin, *System suitability solution*

Tailing factor: 0.8–1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of oxacillin (C₁₉H₁₉N₃O₅S) in the portion of Oxacillin Sodium taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

P = potency of oxacillin in [USP Oxacillin Sodium RS](#) (µg/mg)

Acceptance criteria: 815–950 µg/mg

IMPURITIES

• **ORGANIC IMPURITIES**

Protect solutions containing oxacillin from light.

Solution A: 6 g/L of anhydrous monobasic sodium phosphate, 0.56 g/L of sodium 1-hexanesulfonate monohydrate, and 0.05 g/L of edetate disodium. Adjust with phosphoric acid to a pH of 3.0–3.2.

Solution B: Acetonitrile

Mobile phase: See [Table 2](#).

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	90	10
3	90	10
30	50	50
40	15	85
45	15	85