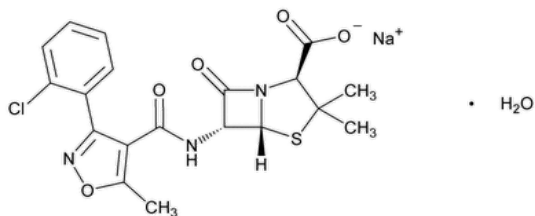


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Cloxacillin Sodium



$C_{19}H_{17}ClN_3NaO_5S \cdot H_2O$ 475.88
4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[[3-(2-chlorophenyl)-5-methyl-4-isoxazolyl]carbonyl]amino]-3,3-dimethyl-7-oxo-, monosodium salt, monohydrate, [2S-(2 α ,5 α ,6 β)];
Monosodium (2S,5R,6R)-6-[3-(o-chlorophenyl)-5-methyl-4-isoxazolecarboxamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate CAS RN[®]: 7081-44-9; UNII: 65LCB00B4Y.
Anhydrous
 $C_{19}H_{17}ClN_3NaO_5S$ 457.87 CAS RN[®]: 642-78-4; UNII: MWQ645MKMF.

DEFINITION
Cloxacillin Sodium contains the equivalent of NLT 825 µg/mg of cloxacillin ($C_{19}H_{18}ClN_3O_5S$).

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, Sodium\(191\)](#): Meets the requirements

ASSAY

• **PROCEDURE**

Protect solutions containing cloxacillin 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 2.9–3.1
Solution B: Acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	45	55
2	45	55
2.5	35	65
5	35	65

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

Diluent: Acetonitrile and water (50:50)

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

System suitability solution: 0.001 mg/mL of [USP Cloxacillin Related Compound D RS](#) from *System suitability stock solution* and 0.1 mg/mL of [USP Cloxacillin Sodium RS](#) in *Diluent*. Store this solution at 4°.

Standard solution: 0.1 mg/mL of [USP Cloxacillin Sodium RS](#) in *Diluent*. Sonicate as needed to dissolve. Store this solution at 4°.

Sample solution: 0.1 mg/mL of Cloxacillin 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: 10 μL

System suitability

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

[NOTE—The relative retention times for cloxacillin and cloxacillin related compound D are about 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between cloxacillin and cloxacillin related compound D, *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 cloxacillin (C₁₉H₁₈ClN₃O₅S) in the portion of Cloxacillin 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 Cloxacillin Sodium RS](#) in the *Standard solution* (mg/mL)

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

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

Acceptance criteria: NLT 825 μg/mg

IMPURITIES

• ORGANIC IMPURITIES

Protect solutions containing cloxacillin from light.

Solution A, Solution B, Diluent, and Chromatographic system: Proceed as directed in the Assay.

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

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	80	20
30	35	65

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

System suitability stock solution: 0.1 mg/mL of [USP Cloxacillin Related Compound D RS](#) in *Diluent*