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## Oxacillin for Injection

### DEFINITION

Oxacillin for Injection contains an amount of Oxacillin Sodium equivalent to NLT 90.0% and NMT 115.0% of the labeled amount of oxacillin ( $C_{19}H_{19}N_3O_5S$ ).

### IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

### ASSAY

#### • PROCEDURE

**Solution A:** 2.7 g/L of monobasic potassium phosphate

**Mobile phase:** Acetonitrile, methanol, and *Solution A* (300:100:700)

**Standard solution:** 0.11 mg/mL of [USP Oxacillin Sodium RS](#). Use on the day prepared.

**Sample solution 1** (where it is represented as being in a single-dose container): Nominally 0.1 mg/mL of oxacillin in water, prepared as follows. Constitute Oxacillin for Injection in a volume of water corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents using a suitable hypodermic needle and syringe, and dilute with water to obtain a solution containing nominally 0.1 mg/mL of oxacillin. Use on the day prepared.

**Sample solution 2** (where the label states the quantity of oxacillin in a given volume of constituted solution): Nominally 0.1 mg/mL of oxacillin in water, prepared as follows. Constitute Oxacillin for Injection with a volume of water corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution with water to obtain a solution containing nominally 0.1 mg/mL of oxacillin. Use on the day prepared.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 225 nm

**Column:** 4-mm  $\times$  30-cm; packing L11

**Flow rate:** 2 mL/min

**Injection volume:** 10  $\mu$ L

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Column efficiency:** NLT 2000 theoretical plates

**Tailing factor:** NMT 1.6

**Relative standard deviation:** NMT 2.0%

#### Analysis

**Samples:** *Standard solution* and *Sample solution 1* or *Sample solution 2*

Calculate the percentage of the labeled amount of oxacillin ( $C_{19}H_{19}N_3O_5S$ ) in the portion of Oxacillin for Injection taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times P \times F \times 100$$

$r_u$  = peak response from *Sample solution 1* or *Sample solution 2*

$r_s$  = peak response from the *Standard solution*

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

$C_u$  = nominal concentration of oxacillin in *Sample solution 1* or *Sample solution 2* (mg/mL)

$P = \text{potency of oxacillin in USP Oxacillin Sodium RS} (\mu\text{g}/\text{mg})$  $F = \text{conversion factor, } 0.001 \text{ mg}/\mu\text{g}$ Where the test for *Uniformity of Dosage Units* has been performed, report the average of the determinations as the Assay value.**Acceptance criteria:** 90.0%–115.0%**PERFORMANCE TESTS**

- **UNIFORMITY OF DOSAGE UNITS (905):** Meets the requirements for *Content Uniformity* for individual containers using *Sample solution 1* or *Sample solution 2*, or both, as appropriate, prepared as directed in the Assay.

**SPECIFIC TESTS**

- **STERILITY TESTS (71):** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **BACTERIAL ENDOTOXINS TEST (85):** It contains NMT 0.2 USP Endotoxin Units/mg of oxacillin.
- **INJECTIONS AND IMPLANTED DRUG PRODUCTS (1), Specific Tests, Completeness and clarity of solutions:** Meets the requirements
- **WATER DETERMINATION (921), Method I:** NMT 6.0%
- **pH (791).**

**Sample solution:** Constitute as directed in the labeling.**Acceptance criteria:** 6.0–8.5

- **PARTICULATE MATTER IN INJECTIONS (788):** Meets the requirements for small-volume injections

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve as described in *Packaging and Storage Requirements (659), Injection Packaging, Packaging for constitution*, at controlled room temperature.
- **USP REFERENCE STANDARDS (11).**  
[USP Oxacillin Sodium RS](#)

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
OXACILLIN FOR INJECTION	<a href="#">Documentary Standards Support</a>	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM12020 Small Molecules 1

**Chromatographic Database Information:** [Chromatographic Database](#)**Most Recently Appeared In:**

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