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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 × 30-cm; packing L11

Flow rate: 2 mL/min

Injection volume: 10 µL

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 = potency of oxacillin in [USP Oxacillin Sodium RS](#) ($\mu\text{g}/\text{mg}$)

F = 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	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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