Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2021
Document Type: USP Monographs
DocId: GUID-2719665B-D516-40AA-9FA4-AF69898CB437_2_en-US
DOI: https://doi.org/10.31003/USPNF_M59047_02_01
DOI Ref: pd9a5

Oxacillin Injection

DEFINITION

Oxacillin Injection is a sterile isoosmotic solution of Oxacillin Sodium in Water for Injection. It contains the equivalent of NLT 90.0% and NMT 115.0% of the labeled amount of oxacillin ($C_{19}H_{19}N_3O_5S$). It contains dextrose as a tonicity-adjusting agent and one or more suitable buffer substances. It contains no preservatives.

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*.

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Dec-2021)

ASSAY

Change to read:

• **Procedure**

Solution A: 2.7 g/L of monobasic potassium phosphate

Mobile phase: Acetonitrile, methanol, and *Solution A* (300:100:700). ▲Adjust with phosphoric acid to a pH of 3.0.▲ (USP 1-Dec-2021)

Standard solution: 0.11 mg/mL of USP Oxacillin Sodium RS. Use this solution on the day prepared.

Sample solution: Nominally 0.1 mg/mL of oxacillin from 1 container of Injection that has been allowed to thaw. Use this solution on the day prepared.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 225 nm.▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Dec-2021)

Column: 4-mm × 30-cm; packing L11

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

▲▲ (USP 1-Dec-2021)

Tailing factor: NMT 1.6

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response ▲of oxacillin▲ (USP 1-Dec-2021) from the *Sample solution*

r_S = peak response ▲of oxacillin▲ (USP 1-Dec-2021) 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 the *Sample solution* (mg/mL)

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

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

Change to read:

• **Sterility Tests ⟨71⟩:** ▲Meets the requirements▲ (USP 1-Dec-2021)

• **pH ⟨791⟩:** 6.0–8.5

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

Change to read:

• **Pyrogen Test ⟨151⟩:** ▲Meets the requirements for a test dose of undiluted Injection equivalent to 20 mg/kg of oxacillin▲ (USP 1-Dec-2021)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*. Maintain in the frozen state.

• **Labeling:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. The label states that it is to be thawed just before use; it describes conditions for proper storage of the resultant solution; it directs that the solution is not to be refrozen.

• **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 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:
Pharmacopeial Forum: Volume No. 46(2)

Current DocID: GUID-2719665B-D516-40AA-9FA4-AF69898CB437_2_en-US
DOI: https://doi.org/10.31003/USPNF_M59047_02_01
DOI ref: pd9a5