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Nafcillin Injection

» Nafcillin Injection is a sterile isoosmotic solution of Nafcillin Sodium and one or more buffer substances in Water for Injection. It contains dextrose as a tonicity-adjusting agent. It contains an amount of nafcillin sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of nafcillin ($C_{21}H_{22}N_2O_5S$). It contains no antimicrobial preservatives.

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#). Maintain in the frozen state.

Labeling—It meets the requirements for [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#). The label states that it is to be thawed just prior to use, describes conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen.

USP REFERENCE STANDARDS (11)—

[USP Nafcillin Sodium RS](#)

Identification—The retention time of the major peak for nafcillin in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the Assay.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.13 USP Endotoxin Unit per mg of nafcillin.

STERILITY TESTS (71)—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH (791): between 6.0 and 8.5.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements for small-volume injections.

Assay—

Acetic acid solution, 0.05 M Sodium acetate, Diluent, Mobile phase, Standard preparation, Resolution solution, and Chromatographic system—Proceed as directed in the Assay under [Nafcillin Sodium](#).

Assay preparation—Allow one container of Injection to thaw, and mix. Transfer an accurately measured volume of Injection, equivalent to about 40 mg of nafcillin, to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the [Assay](#) under [Nafcillin Sodium](#). Calculate the quantity, in mg, of nafcillin ($C_{21}H_{22}N_2O_5S$) in each mL of the Injection taken by the formula:

$$0.1(C/V)(r_U/r_S)$$

in which *C* is the concentration, in µg per mL, of nafcillin in the *Standard preparation*; *V* is the volume, in mL, of Injection taken to prepare the *Assay preparation*; and *r_U* and *r_S* are the nafcillin peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
NAFCILLIN 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](#)

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