

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2018
 Document Type: USP Monographs
 DocId: GUID-049C00DB-7307-4E5B-ABA0-DB5366F77C50_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M55229_03_01
 DOI Ref: 85wwf

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Nafcillin for Injection

» Nafcillin for Injection 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 ($C_{21}H_{22}N_2O_5S$).

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#), [Packaging for constitution](#).

USP REFERENCE STANDARDS (11)—

[USP Nafcillin Sodium RS](#)

Constituted solution—At the time of use, it meets the requirements for [Injections and Implanted Drug Products \(1\)](#), [Specific Tests, Completeness and clarity of solutions](#).

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, in the solution constituted as directed in the labeling.

WATER DETERMINATION, Method I (921): between 3.5% and 5.3%.

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

Other requirements—It meets the requirements for [Uniformity of Dosage Units \(905\)](#) and [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#).

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 1 (where it is represented as being in a single-dose container)—Constitute Nafcillin for Injection in a volume of water, accurately measured, 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 quantitatively with *Diluent* to obtain a solution having a concentration of about 0.4 mg of nafcillin ($C_{21}H_{22}N_2O_5S$) per mL.

Assay preparation 2 (where the label states the quantity of nafcillin in a given volume of constituted solution)—Constitute Nafcillin for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with *Diluent* to obtain a solution having a concentration of about 0.4 mg of nafcillin ($C_{21}H_{22}N_2O_5S$) per mL.

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 the portion of constituted Nafcillin for Injection taken by the formula:

$$(C/1000)(L/D)(r_f/r_s)$$

in which *L* is the labeled quantity, in mg, of nafcillin in the portion of Nafcillin for Injection taken; *D* is the concentration, in mg per mL, of nafcillin in *Assay preparation 1* or *Assay preparation 2*, as appropriate, based on the volume of constituted Nafcillin for Injection taken and the extent of dilution; and the other terms are as defined therein.

Perform the above procedure on 10 containers where it is represented as being in a single-dose container and, if necessary, on 10 containers where the label states the quantity of nafcillin in a given volume of constituted solution. Use the individual results to determine the *Uniformity of dosage units* and the average thereof as the Assay value.

Topic/Question	Contact	Expert Committee
NAFCILLIN 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:
Pharmacopeial Forum: Volume No. 46(2)

Current DocID: GUID-049C00DB-7307-4E5B-ABA0-DB5366F77C50_3_en-US
Previous DocID: GUID-049C00DB-7307-4E5B-ABA0-DB5366F77C50_1_en-US
DOI: https://doi.org/10.31003/USPNF_M55229_03_01
DOI ref: [85wwf](#)

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