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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:

$$(C/1000)(L/D)(r_U/r_S)$$

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

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