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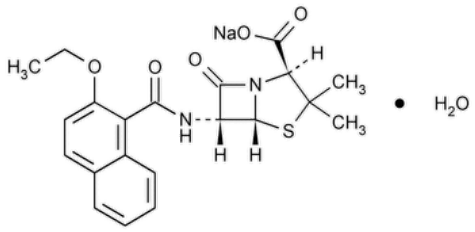
Nafcillin Sodium



$C_{21}H_{21}N_2NaO_5S \cdot H_2O$ 454.47

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[(2-ethoxy-1-naphthalenyl)carbonyl]amino]-3,3-dimethyl-7-oxo-, monosodium salt, monohydrate, [2*S*-(2α,5α,6β)].

Monosodium (2*S*,5*R*,6*R*)-6-(2-ethoxy-1-naphthamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate CAS RN®: 7177-50-6; UNII: 49G3001BCK.

Anhydrous 436.47 CAS RN®: 985-16-0; UNII: SY07234TTS.

» Nafcillin Sodium has a potency equivalent to not less than 820 µg of nafcillin ($C_{21}H_{22}N_2O_5S$) per mg.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

USP Reference standards ⟨11⟩—

USP Nafcillin Sodium RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 50 µg per mL.

Medium: water.

B: 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*.

C: It responds to the tests for *Sodium* ⟨191⟩.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 5.0 and 7.0, in a solution containing 30 mg per mL.

Water Determination, *Method I* ⟨921⟩: between 3.5% and 5.3%.

Other requirements—Where the label states that Nafcillin Sodium is sterile, it meets the requirements for *Sterility Tests* ⟨71⟩ and for *Bacterial endotoxins* under *Nafcillin for Injection*. Where the label states that Nafcillin Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Nafcillin for Injection*.

Assay—

Acetic acid solution—Prepare a 1 in 20 solution of glacial acetic acid and water.

0.05 M Sodium acetate—Dissolve 6.8 g of sodium acetate in about 800 mL of water, adjust with *Acetic acid solution* to a pH of 7.5, dilute with water to 1000 mL, and mix.

Mobile phase—Prepare a suitable filtered and degassed mixture of *0.05 M Sodium acetate* and acetonitrile (70:30). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluent—Dissolve 6.9 g of sodium citrate in about 800 mL of water, adjust with 1 N hydrochloric acid to a pH of 7.0, dilute with water to 1000 mL, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Nafcillin Sodium RS quantitatively in *Diluent* to obtain a solution having a known concentration of about 400 µg of nafcillin ($C_{21}H_{22}N_2O_5S$) per mL.

Resolution solution—Prepare a solution of orcinol in water containing about 35 mg per mL. Add 0.5 mL of this solution to 25 mL of *Standard preparation* to obtain a solution containing about 0.7 mg of orcinol and 400 µg of nafcillin per mL.

Assay preparation—Transfer about 88 mg of Nafcillin Sodium, accurately weighed, to a 200-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column containing packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.8 for orcinol and 1.0 for nafcillin; and the resolution between the orcinol and nafcillin peaks is not less than 2.0. Chromatograph the *Standard preparation*, and record the responses as directed for *Procedure:* the tailing factor for the analyte peak is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%. *Procedure*—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg, of nafcillin ($C_{21}H_{22}N_2O_5S$) in each mg of Nafcillin Sodium taken by the formula:

$$200(C/W)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of nafcillin ($C_{21}H_{22}N_2O_5S$) in the *Standard preparation; W* is the weight, in mg, of the portion of Nafcillin Sodium taken; 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 SODIUM	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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