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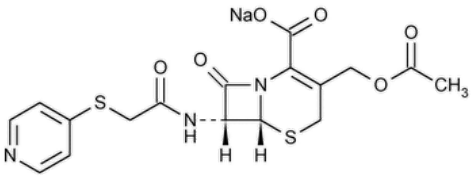
Cephapirin Sodium



$C_{17}H_{16}N_3NaO_6S_2$ 445.45

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[(acetyl-oxy)methyl]-8-oxo-7-[[(4-pyridinylthio)ace tyl]amino]-, monosodium salt, (6*R*-*trans*)-.

Monosodium (6*R*,7*R*)-3-(hydroxymethyl)-8-oxo-7-[2-(4-pyridylthio)acetamido]-5-thia-1-azabicyclo-[4.2.0] oct-2-ene-2-carboxylate acetate (ester) CAS RN®: 24356-60-3; UNII: 431LFF7I7J.

» Cephapirin Sodium has a potency equivalent to not less than 855 µg and not more than 1000 µg of cephapirin ($C_{17}H_{17}N_3O_6S_2$) 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 Cephapirin Sodium RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

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

Crystallinity ⟨695⟩**:** meets the requirements.

pH ⟨791⟩**:** between 6.5 and 8.5, in a solution containing 10 mg of cephapirin per mL.

Water Determination, *Method I* ⟨921⟩**:** not more than 2.0%.

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

Assay—

Solution A, Solution B, Mobile phase, Extraction solution, Dilution buffer, 10% Acetic acid solution, System suitability solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Cephapirin Benzathine.*

Assay preparation—In duplicate, weigh about 50 mg of Cephapirin Sodium, and transfer into a 25-mL volumetric flask. Add about 2.5 mL of *Extraction solution* and 15.0 mL of *Dilution buffer,* and mix to dissolve. Add 7.0 mL of acetonitrile, and mix. Allow the flask to return to room temperature, and dilute with water to volume.

Procedure—Separately inject equal volumes (about 2 µL) of the duplicate *Standard preparation* and the duplicate *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in µg, of cephapirin ($C_{17}H_{17}N_3O_6S_2$) in each mg of Cephapirin Sodium taken by the formula:

$$P(W_S/W_U)(V_U/V_S)(r_U/r_S)$$

in which P is the assigned potency, in µg of cephapirin per mg, of USP Cephapirin Sodium RS; W_S and W_U are the quantities of USP Cephapirin Sodium RS and Cephapirin Sodium, in mg, used to prepare the *Standard preparation* and the *Assay preparation,* respectively; V_U and V_S are the final volumes, in mL, of the *Assay preparation* and the *Standard preparation,* respectively; and r_U and r_S are the average peak areas of the cephapirin peaks obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
CEPHAPIRIN SODIUM	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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