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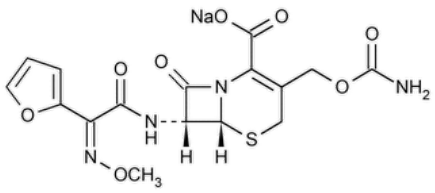
Cefuroxime Sodium



$C_{16}H_{15}N_4NaO_8S$ 446.37

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[(aminocarbonyl)oxy]methyl]-7-[[2-furanyl(methoxyimino)acetyl]amino]-8-oxo-, monosodium salt [6*R*-[6α,7β(*Z*)]]-.

Sodium (6*R*,7*R*)-7-[2-(2-furyl)glyoxylamido]-3-(hydroxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate, 7^2-(*Z*)-(*O*-methyloxime), carbamate (ester) CAS RN®: 56238-63-2; UNII: R8A7M9MY61.

» Cefuroxime Sodium contains the equivalent of not less than 855 µg and not more than 1000 µg of cefuroxime ($C_{16}H_{16}N_4O_8S$), calculated on the anhydrous basis.

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 Cefuroxime Sodium RS

Identification—

A: The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for cefuroxime, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation* obtained as directed in the *Assay*.

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

pH ⟨791⟩**:** between 6.0 and 8.5, in a solution (1 in 10).

Water Determination, *Method I* ⟨921⟩**:** not more than 3.5%.

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

Assay—

pH 3.4 acetate buffer—Transfer 50 mL of 0.1 M sodium acetate to a 1000-mL volumetric flask, dilute with 0.1 N acetic acid to volume, and mix.

Mobile phase—Prepare a suitable mixture of *pH 3.4 acetate buffer* and acetonitrile (about 10:1). Filter through a membrane filter (1 µm or finer porosity), and degas.

Internal standard solution—Prepare a solution of orcinol in water containing 1.5 mg per mL.

Standard preparation—Dissolve a suitable quantity of USP Cefuroxime Sodium RS, accurately weighed, in water to obtain a solution having a known concentration of about 1 mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per mL. Immediately transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 20.0 mL of *Internal standard solution*, dilute with water to volume, and mix. This *Standard preparation* contains about 0.05 mg of cefuroxime per mL.

Assay preparation—Using a suitable quantity of Cefuroxime Sodium, accurately weighed, proceed as directed in the first sentence under *Standard preparation.* Immediately transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 20.0 mL of *Internal standard solution*, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 15-cm column that contains 5-µm packing L15. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the column efficiency determined from the analyte peak is not less than 1300 theoretical plates; the tailing factor for the analyte peak is not more than 2.0; the resolution, *R,* between the analyte and internal standard peaks is not less than 3.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.5 for cefuroxime and 1.0

for orcinol. Calculate the quantity, in µg, of cefuroxime per mg of the Cefuroxime Sodium taken by the formula:

$$1000(C/M)(R_U/R_S)$$

in which C is the concentration, in mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per mL, in the *Standard preparation;* M is the concentration, in mg per mL, in the *Assay preparation* based on the weight of Cefuroxime Sodium taken and the extent of dilution; and R_U and R_S are the peak response ratios of the cefuroxime peak to the internal standard peak 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
CEFUROXIME SODIUM	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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