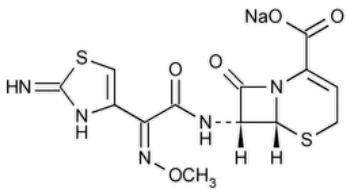
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-1FEF1E96-0DD5-4BA9-A5C7-E362069EAD64_3_en-US
DOI: https://doi.org/10.31003/USPNF_M14139_03_01
DOI Ref: u3jl4

Ceftizoxime Sodium



$C_{13}H_{12}N_5NaO_5S_2$ 405.38

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[(2,3-dihydro-2-imino-4-thiazoly)(methoxyimino)acetyl]amino]-8-oxomonosodium salt, [6*R*-[6α,7β(*Z*)]]-.

Sodium (6*R*,7*R*)-7-[2-(2-imino-4-thiazolin-4-yl)glyoxylamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate 7^2-(*Z*)-(*O*-methyloxime) CAS RN®: 68401-82-1; UNII: 26337D5X88.

» Ceftizoxime Sodium contains the equivalent of not less than 850 µg and not more than 995 µg of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) per mg, 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 Ceftizoxime RS

Identification—

A: The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for ceftizoxime, 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⟩.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 6.0 and 8.0, in a solution (1 in 10).

Water Determination, *Method I* ⟨921⟩: not more than 8.5%.

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

Assay—

pH 3.6 Buffer—Dissolve 1.42 g of citric acid monohydrate and 1.73 g of dibasic sodium phosphate in water to obtain 1000 mL of solution.

pH 7.0 Buffer—Dissolve 3.63 g of monobasic potassium phosphate and 10.73 g of dibasic sodium phosphate in water to obtain 1000 mL of solution.

Mobile phase—Prepare a mixture of *pH 3.6 Buffer* and acetonitrile (about 9:1). Filter through a filter (1 µm or finer porosity), and degas. Adjust the composition, if necessary, to meet the performance requirements under *Chromatographic system*.

Internal standard solution—Dissolve 1.2 g of salicylic acid in 10 mL of methanol, and dilute with *pH 7.0 Buffer* to obtain 200 mL of solution.

Standard preparation—Dissolve a suitable quantity of USP Ceftizoxime RS, accurately weighed, in *pH 7.0 Buffer* to obtain a solution having a known concentration of about 1 mg of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) per mL. Transfer 2.0 mL of this solution to a 100-mL volumetric flask, add 5.0 mL of *Internal standard solution*, dilute with *pH 7.0 Buffer* to volume, and mix. This *Standard preparation* contains about 0.02 mg of ceftizoxime per mL.

Assay preparation—Using a suitable quantity of Ceftizoxime Sodium, accurately weighed, proceed as directed under *Standard preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.0-mm × 30-cm column that contains 5- to 10-µm packing L1. 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 2000 theoretical plates; the tailing factor for the analyte peak is not more than 2, the resolution; *R,* between the analyte and internal standard peaks is not less than 4; and the relative standard deviation for replicate injections is not more than 2%.

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 0.6 for ceftizoxime and

1.0 for salicylic acid. Calculate the quantity, in µg, of ceftizoxime per mg of the Ceftizoxime Sodium taken by the formula:

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

in which C is the concentration, in mg of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) per mL, of the *Standard preparation; M* is the concentration, in mg per mL, of the *Assay preparation* based on the weight of Ceftizoxime Sodium taken and the extent of dilution; and R_U and R_S are the peak response ratios of the ceftizoxime 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
CEFTIZOXIME SODIUM	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(4)

Current DocID: GUID-1FEF1E96-0DD5-4BA9-A5C7-E362069EAD64_3_en-US
Previous DocID: GUID-1FEF1E96-0DD5-4BA9-A5C7-E362069EAD64_1_en-US
DOI: https://doi.org/10.31003/USPNF_M14139_03_01
DOI ref: u3jl4