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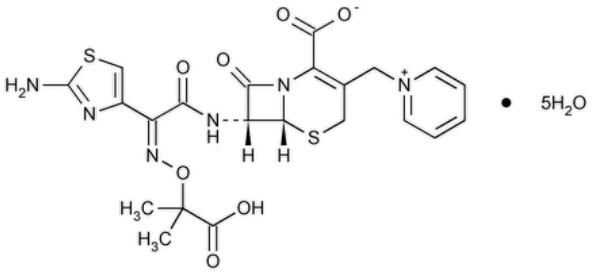
Ceftazidime



$C_{22}H_{22}N_6O_7S_2 \cdot 5H_2O$ 636.65

Pyridinium, 1-[[7-[[(2-amino-4-thiazolyl)[(1-carboxy-1-methylethoxy)imino]acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-, hydroxide, inner salt, pentahydrate, [6*R*[6α,7β(*Z*)]]-.

1-[[(6*R*,7*R*)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en–3-yl]methyl]pyridinium hydroxide, inner salt, 7^2-(*Z*)-[*O*(1-carboxy-1-methylethyl)oxime], pentahydrate CAS RN®: 78439-06-2; UNII: 9M416Z9QNR.

Anhydrous 546.59

» Ceftazidime contains not less than 95.0 percent and not more than 102.0 percent of $C_{22}H_{22}N_6O_7S_2$, calculated on the dried 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 or other sterile dosage forms.

USP Reference standards ⟨11⟩—

USP Ceftazidime, Delta-3-Isomer RS
USP Ceftazidime Pentahydrate RS

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

Crystallinity ⟨695⟩: meets the requirements.

Sterility Tests ⟨71⟩ —Where the label states that it is sterile, it meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*, except to use *Fluid A* to each 1000 mL of which has been added 10 g of sodium bicarbonate before sterilization.

pH ⟨791⟩: between 3.0 and 4.0, in a solution containing 5 mg per mL.

Loss on drying ⟨731⟩—Dry about 300 mg, accurately weighed, in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses between 13.0% and 15.0% of its weight.

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

Assay—

pH 7 Buffer—Dissolve 42.59 g of anhydrous dibasic sodium phosphate and 27.22 g of monobasic potassium phosphate in water to make 1000 mL of solution.

Mobile phase—Mix 40 mL of acetonitrile and 200 mL of *pH 7 Buffer*, and dilute with water to obtain 2000 mL of solution. Filter, using a filter having a porosity of 1 µm or finer, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 29 mg of USP Ceftazidime Pentahydrate RS, accurately weighed, to a 25-mL volumetric flask containing 2.5 mL of *pH 7 Buffer,* and shake until dissolved. Dilute with water to volume, and mix. [Note—Protect this solution from light.] Immediately prior to chromatography, transfer 5.0 mL of this stock solution to a 50-mL volumetric flask, dilute with water to volume, and mix. This solution contains about 100 µg of ceftazidime ($C_{22}H_{22}N_6O_7S_2$) per mL.

Assay preparation—Transfer about 115 mg of Ceftazidime, accurately weighed, to a 100-mL volumetric flask containing 10.0 mL of *pH 7 Buffer,* and shake until dissolved. Dilute with water to volume, and mix. [Note—Protect this solution from light.] Immediately prior to chromatography, transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with water to volume, and mix.

Resolution solution—Prepare a solution of USP Ceftazidime, Delta-3-Isomer RS in *pH 7 Buffer* containing about 0.1 mg per mL. Immediately prior to chromatography, mix 1 mL of this solution with 8 mL of water and 1 mL of the stock solution used to prepare the *Standard preparation.*

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 L1. The flow rate is about 2 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between ceftazidime and ceftazidime, delta-3-isomer 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 less than 0.75 and not more than 1.5, and the relative standard deviation for replicate injections is not more than 1.0%.

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 mg, of $C_{22}H_{22}N_6O_7S_2$ in the portion of Ceftazidime taken by the formula:

$$C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of ceftazidime ($C_{22}H_{22}N_6O_7S_2$) in the *Standard preparation;* and r_U and r_S are the 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
CEFTAZIDIME	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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