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Ceftazidime Injection

» Ceftazidime Injection is a sterile isoosmotic solution of Ceftazidime in Water for Injection. It contains one or more suitable buffers and a tonicity-adjusting agent. It contains not less than 90.0 percent and not more than 120.0 percent of the labeled amount of $C_{22}H_{22}N_6O_7S_2$.

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*. Maintain in the frozen state.

Labeling—It meets the requirements for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. The label states that it is to be thawed just prior to use, describes conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen.

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* obtained as directed in the *Assay.*

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.1 USP Endotoxin Unit per mg of ceftazidime.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 5.0 and 7.5.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Assay—

pH 7 Buffer, Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Ceftazidime.*

Assay preparation—Allow a container of the Injection to thaw, and mix the solution. Transfer an accurately measured volume of the Injection, equivalent to about 50 mg of ceftazidime, to a 50-mL volumetric flask, dilute with *pH 7 buffer* to volume, and mix. Transfer 5.0 mL of this solution to a second 50-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Ceftazidime.* Calculate the quantity, in mg, of $C_{22}H_{22}N_6O_7S_2$ in each mL of the Injection taken by the formula:

$$0.5(C/V)(r_U/r_S)$$

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

Chromatographic Database Information: Chromatographic Database

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