sponds for the major peaks. Calculate the per centage of arginine (C_{6}H_{14}N_{4}O_{2}) in the Ceftazidime for Injection taken by the formula:

$$100(C_{i} / C_{o})_{\text{per cent}}$$

in which $C_{i}$ is the concentration, in mg per mL, of USP L-Arginine RS in the Standard preparation; $C_{o}$ is the concentration, in mg per mL, of Ceftazidime for Injection in the Test preparation, based on the weight, in mg, of Ceftazidime for Injection taken and the extent of dilution; and $r_{i}$ and $r_{o}$ are the arginine peak responses obtained from the Test preparation and the Standard preparation, respectively. Use this per centage to calculate, on the anhydrous and arginine-free basis, the assay result from Assay preparation 1 obtained as directed in the Assay.

**Other requirements**—It meets the requirements for Uniformity of Dosage Units (905) and for Labeling under Injections (1).

**Assay**—

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

**Assay preparation 1**—Transfer an accurately weighed quantity of Ceftazidime for Injection, equivalent to about 250 mg of ceftazidime (C_{22}H_{22}N_{6}O_{7}S_{2}), to a 250-mL volumetric flask, dilute with water to volume, and mix to obtain a stock solution. [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.

**Assay preparation 2** (where it is represented as being in a single-dose container) —Constitute a container of Ceftazidime for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with water to obtain a solution containing about 1 mg of ceftazidime (C_{22}H_{22}N_{6}O_{7}S_{2}) per mL. [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.

**Assay preparation 3** (where the label states the quantity of ceftazidime in a given volume of constituted solution) —Constitute a container of Ceftazidime for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with water to obtain a solution containing about 1 mg of ceftazidime (C_{22}H_{22}N_{6}O_{7}S_{2}) per mL. [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.

**Procedure**—Proceed as directed for Procedure in the Assay under Ceftazidime. Calculate the per centage of ceftazidime (C_{22}H_{22}N_{6}O_{7}S_{2}) on the dried and sodium carbonate-free or arginine-free basis in the portion of Ceftazidime for Injection taken by the formula:

$$\frac{(100 \times C_{i} / C_{o})_{\text{per cent}}}{D}$$

in which $C_{i}$ is the concentration, in $\mu$g per mL, of ceftazidime (C_{22}H_{22}N_{6}O_{7}S_{2}) in the chromatogram of the Constituted solution taken; and $D$ is the concentration, in $\mu$g of ceftazidime (C_{22}H_{22}N_{6}O_{7}S_{2}) per mL, of Assay preparation 2 or Assay preparation 3, based on the labeled quantity in the container or in the portion of constituted solution taken, respectively, and the extent of dilution.

**Ceftizoxime Sodium**

- **C_{13}H_{12}N_{5}NaO_{5}S_{2} 405.39**
- **Sodium (6
- **Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[(2,3-dihydro-2-imino-4-thiazoly)(methoxyimino)acetyl]amino]-8-oxomonomosodium salt: [6 R,6S]-6-[(6R,7S)-7-[2-(2-imino-4-thiazolin-4-yl)glyoxyxalamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-carboxylate 7-2]-Z-(O-methyloxime) [68401-82-1]**

> Ceftizoxime Sodium contains the equivalent of not less than 850 $\mu$g and not more than 995 $\mu$g of ceftizoxime (C_{13}H_{12}N_{5}O_{5}S_{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**
- **USP Endotoxin 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, 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 acetone:water (about 9:1). Filter through a filter (1 $\mu$m 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.

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Ceftizoxime Injection

Ceftizoxime Injection is a sterile solution of Ceftizoxime Sodium in a diluent containing one or more tonicity-adjusting agents in Water for Injections. It contains the equivalent of not less than 90.0 percent and not more than 115.0 percent of the labeled amount of ceftizoxime (C13H13N5O5S2).

Packaging and storage—Preserve in Containers for Injections as described under Injections (1). Maintain in the frozen state.

Labeling—It meets the requirements for Labeling under Injections (1). 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 Ceftizoxime RS
USP Endotoxin RS

Identification—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.

Bacterial endotoxins (85)—It contains not more than 0.10 USP Endotoxin Unit per mg of ceftizoxime.

Sterility (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 5.5 and 8.0.

Particulate matter (788): meets the requirements for small-volume injections.

Assay—

pH 3.6 Buffer, pH 7.0 Buffer, Mobile phase, Internal standard solution, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under Ceftizoxime Sodium.

Assay preparation—Allow 1 container of Injection to thaw, and mix. Transfer an accurately measured volume of the Injection, equivalent to about 40 mg of ceftizoxime, to a 100-mL volumetric flask, dilute with pH 7.0 Buffer to volume, and mix. Transfer 5.0 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. Procedure—Proceed as directed for Procedure in the Assay under Ceftizoxime Sodium. Calculate the quantity, in mg, of ceftizoxime (C13H13N5O5S2) in each mL of the Injection taken by the formula:

\[
2000 \left( \frac{C}{V} \right) (R_1 / R_2)
\]

in which \( C \) is the concentration, in mg of ceftizoxime (C13H13N5O5S2) 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; \( R_1 \) and \( R_2 \) are the peak response ratios of the ceftizoxime peak to the internal standard peak obtained from the Assay preparation and the Standard preparation, respectively.