isomer and cefprozil *(E)*-isomer in each mL of the Cefprozil for Oral Suspension taken by the formula:

$$0.833(CP/V)(r_U / r_S)$$

in which *V* is the volume, in mL, of Cefprozil for Oral Suspension taken, and the other terms are as defined therein. Calculate the quantity, in mg, of cefprozil ($C_{18}H_{19}N_3O_5S$) in each mL of Cefprozil for Oral Suspension taken by adding the values, in mg per mL, obtained from the cefprozil *(Z)*-isomer and from the cefprozil *(E)*-isomer.

Cefprozil Tablets

» Cefprozil Tablets contain not less than 90.0 percent and not more than 120.0 per cent of the labeled amount of cefprozil ($C_{18}H_{19}N_3O_5S$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Cefprozil (*Z*)-Isomer RS
USP Cefprozil (*E*)-Isomer RS

Identification—

A: Place a Tablet in a mixture of acetone and 0.1 N hydrochloric acid (4:1) of sufficient volume to obtain a solution containing 2.5 mg of cefprozil per mL, shake for 5 minutes, and allow the mixture to settle. Proceed as directed for *Identification* test *A* under *Cefprozil for Oral Suspension*, beginning with "Use the supernatant as the *Test solution*." The specified result is obtained.

B: The retention times of the cefprozil (*Z*)-isomer and cefprozil (*E*)-isomer peaks in the chromatogram of the *Assay preparation* correspond to those of the *Standard preparations*, as obtained in the *Assay*.

Dissolution ⟨711⟩**—**

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of cefprozil ($C_{18}H_{19}N_3O_5S$) dissolved in the *Dissolution Medium*, as directed in the *Assay*, using instead of the *Assay preparation* a filtered portion of the *Dissolution Medium*, diluted if necessary, to obtain a test solution containing about 0.3 mg of cefprozil per mL. Calculate the quantity, in mg, of cefprozil (*Z*)-isomer and cefprozil (*E*)-isomer dissolved by the formula:

$$0.9(CPD)(r_U / r_S)$$

in which *D* is 1 or, where the filtered *Dissolution Medium* was diluted to prepare the test solution, the appropriate dilution factor, and the other terms are as defined therein. Calculate the quantity, in mg, of cefprozil ($C_{18}H_{19}N_3O_5S$) dissolved by adding the quantity, in mg, of the cefprozil (*Z*)-isomer and cefprozil (*E*)-isomer dissolved.

Tolerances—Not less than 75% *(Q)* of the labeled amount of cefprozil ($C_{18}H_{19}N_3O_5S$) is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩**—**meet the requirements.

Water, *Method I* ⟨921⟩: not more than 7.0%.

Assay—

Mobile phase, Cefprozil (*Z*)*-isomer standard preparation, Cefprozil* (*E*)*-isomer standard preparation, Resolution solution*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Cefprozil.*

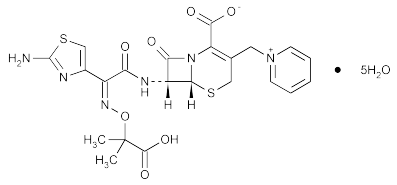
Assay preparation—Transfer an accurately counted number of Tablets, equivalent to about 1500 mg of cefprozil, to a 250-mL volumetric flask containing about 180 mL of water. Allow the Tablets to disintegrate with the aid of swirling and sonication. Dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix. Filter a portion of this solution through a filter having a porosity of 0.5 µm or finer, and use the filtrate as the *Assay preparation.* [NOTE—Use this solution within 6 hours.]

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Cefprozil.* Calculate the quantity, in mg, of cefprozil (*Z*)-isomer and cefprozil (*E*)-isomer in each Tablet taken by the formula:

$$5(CP / N)(r_U / r_S)$$

in which *N* is the number of Tablets taken, and the other terms are as defined therein. Calculate the quantity, in mg, of cefprozil ($C_{18}H_{19}N_3O_5S$) taken by adding quantities, in mg, determined for the cefprozil (*Z*)-isomer and for the cefprozil (*E*)-isomer in each Tablet.

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 [78439-06-2].

Anhydrous 546.59

» Ceftazidime contains not less than 95.0 per cent and not more than 102.0 per cent 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
USP Endotoxin 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 ⟨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.