

(3) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 0.7 milligram per milliliter.

(4) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

(5) *Specific rotation*. Dissolve and dilute an accurately weighed sample with sufficient 2 percent sodium bicarbonate to obtain a concentration of approximately 10 milligrams of cefixime per milliliter. Proceed as directed in § 436.210 of this chapter, using a 1.0-decimeter polarimeter tube. Calculate the specific rotation on the anhydrous basis.

(6) *Identity*. Proceed as directed in § 436.211 of this chapter, using a potassium bromide disc containing 0.5 percent of cefixime. Dissolve 5 to 6 milligrams of cefixime in 2 milliliters of methanol. Triturate to insure solution. Evaporate the solvent to dryness and using the dried sample, prepare the potassium bromide disc.

[53 FR 24257, June 28, 1988; 53 FR 26712, July 14, 1988; 54 FR 47205, Nov. 13, 1989]

§ 442.16 Cefazidime pentahydrate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Cefazidime pentahydrate is 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, [6*R*-[6 α ,7 β (*Z*)]]-, pentahydrate. It is so purified and dried that:

(i) Its potency is not less than 950 micrograms and not more than 1,020 micrograms of cefazidime activity per milligram on an anhydrous basis.

(ii) Its loss on drying is not less than 13.0 percent and not more than 15.0 percent.

(iii) The pH of an aqueous solution containing 5 milligrams of cefazidime per milliliter is not less than 3.0 and not more than 4.0.

(iv) It is crystalline.

(v) It gives a positive identity test for cefazidime.

(vi) Its high molecular weight polymer content is not more than 0.05 percent.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples*. In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, loss on drying, pH, crystallinity, identity, and high molecular weight polymer content.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay—(1) Potency*. Proceed as directed in § 442.16a(b)(1).

(2) *Loss on drying*. Proceed as directed in § 436.200(a) of this chapter.

(3) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 5 milligrams of ceftazidime per milliliter.

(4) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

(5) *Identity*. The high performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the ceftazidime working standard.

(6) *High molecular weight polymer content*. Proceed as directed in § 442.16a(b)(8).

[54 FR 40652, Oct. 3, 1989]

§ 442.16a Sterile ceftazidime pentahydrate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Sterile ceftazidime pentahydrate is 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, [6*R*-[6 α , 7 β (*Z*)]]-, pentahydrate. It is so purified and dried that:

(i) Its potency is not less than 950 micrograms and not more than 1,020 micrograms of ceftazidime activity per milligram on an anhydrous basis.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) Its loss on drying is not less than 13.0 and not more than 15.0 percent.