

§ 442.253

standard;
 P_s =Ceforanide activity in the ceforanide working standard solution in micrograms per milliliter;
 C_u =Milligrams of sample per milliliter of sample solution; and
 L =Percent lysine content of the sample. (Determined as described in § 436.349 of this chapter.)

(b) *Milligrams of ceforanide per vial.* Calculate the ceforanide content of the vial as follows:

$$\text{Milligrams of ceforanide per vial} = \frac{A_s \times P_s \times d}{A_s \times 1,000}$$

where:

A_u =Area of the ceforanide sample peak (at a retention time equal to that observed for the standard);
 A_s =Area of the ceforanide peak in the chromatogram of the ceforanide working standard;
 P_s =Ceforanide activity in the ceforanide working standard solution in micrograms per milliliter; and
 d =Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except reconstitute the vials with approximately 3.0 milliliters of diluting fluid A per each gram of antibiotic activity. Transfer approximately 1 milliliter from each of 20 vials into a sterile 500-milliliter Erlenmeyer flask containing 200 milliliters of diluting fluid A. Filter as described in paragraph (e)(1)(ii) of this section, except in lieu of filtering with three 100-milliliter quantities of diluting fluid A, rinse the filter membrane with three 100-milliliter portions of diluting fluid D followed by a final rinse with 100 milliliters of diluting fluid A.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 50 milligrams of ceforanide per milliliter.

(4) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution obtained when the product is reconstituted as directed in the labeling.

[49 FR 25848, June 25, 1984; 49 FR 34347, Aug. 30, 1984; 49 FR 40006, Oct. 12, 1984, as amended at 55 FR 11583, Mar. 29, 1990]

§ 442.253 Cefotetan injectable dosage forms.

§ 442.253a Sterile cefotetan disodium.

The requirements for certification and the tests and methods of assay for sterile cefotetan disodium packaged for dispensing are described in § 442.53a.

[51 FR 20264, June 4, 1986. Redesignated at 59 FR 26941, May 25, 1994]

§ 442.253b Cefotetan sodium injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefotetan sodium injection is a frozen, aqueous, iso-osmotic solution of cefotetan and sodium bicarbonate. It contains one or more suitable and harmless buffer substances and a tonicity adjusting agent. Each milliliter contains cefotetan disodium equivalent to 20 milligrams or 40 milligrams of cefotetan per milliliter. Its cefotetan content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefotetan that it is represented to contain. It is sterile. It contains not more than 0.17 endotoxin units per milligram of cefotetan. Its pH is not less than 4.0 and not more than 6.5. It passes the identity test. The cefotetan used conforms to the standards prescribed by § 442.52(a)(1).

(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:

(A) The cefotetan used in making the batch for cefotetan potency, moisture, and identity.

(B) The batch for cefotetan potency, sterility, bacterial endotoxins, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefotetan used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch:

(1) For all tests except sterility: A minimum of 12 immediate containers.