

**§ 442.213 Cefotaxime injectable dosage forms.****§ 442.213a Sterile cefotaxime sodium.**

The requirements for certification and the tests and methods of assay for sterile cefotaxime sodium packaged for dispensing are described in § 442.13a.

[46 FR 25607, May 8, 1981. Redesignated at 50 FR 45109, Oct. 30, 1985]

**§ 442.213b Cefotaxime sodium injection.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefotaxime sodium injection is a frozen aqueous solution of cefotaxime sodium with one or more suitable and harmless buffer substances in an isosmotic diluent. Each milliliter contains cefotaxime sodium equivalent to either 20 milligrams or 40 milligrams of cefotaxime per milliliter. Its cefotaxime content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of cefotaxime that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 5.0 and not more than 7.5. It passes the identity test. The cefotaxime sodium used conforms to the standards prescribed by § 442.13(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 cefotaxime sodium used in making the batch for potency, moisture, pH, and identity.

(b) The batch for potency, sterility, pyrogens, pH, and identity.

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

(a) The cefotaxime sodium used in making the batch: 10 packages, each containing approximately 500 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay.* Thaw the sample as directed in the labeling. The sample solution used for testing must be at room temperature.

(1) *Potency.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Using a suitable hypodermic needle and syringe, remove an accurately measured representative portion from each container and dilute with sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 2.0 micrograms of cefotaxime per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter, preparing the sample as follows: Using a suitable hypodermic needle and syringe, remove an accurately measured representative portion from each container and dilute with distilled water to give a stock solution of convenient concentration. Further dilute with distilled water to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, except inject a sufficient volume of the undiluted solution to deliver 50 milligrams of cefotaxime per kilogram.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

(5) *Identity.* Proceed as directed in § 436.323 of this chapter, except prepare spotting solutions as follows: Prepare solutions of the sample and working standard, each containing 1 milligram of cefotaxime per milliliter in distilled water.

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