

§ 442.214 Cefoxitin injectable dosage forms.**§ 442.214a Sterile cefoxitin sodium.**

The requirements for certification and the tests and methods of assay for sterile cefoxitin packaged for dispensing are described in § 442.14a.

[44 FR 10376, Feb. 20, 1979. Redesignated at 49 FR 47827, Dec. 7, 1984]

§ 442.214b Cefoxitin sodium injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefoxitin sodium injection is a frozen aqueous solution of cefoxitin sodium with one or more suitable and harmless buffer substances in an isotonic diluent. Each milliliter contains cefoxitin sodium equivalent to either 20 or 40 milligrams of cefoxitin. Its cefoxitin content is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of cefoxitin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 4.5 and not more than 8.0. It passes the identity test. The cefoxitin sodium used conforms to the standards prescribed by § 442.14(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 cefoxitin sodium used in making the batch for cefoxitin content, moisture, pH, identity, and crystallinity.

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

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

(a) The cefoxitin 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) *Cefoxitin content.* Proceed as directed in § 436.347 of this chapter, preparing the working standard and sample solutions and calculating the cefoxitin content as follows:

(i) *Working standard solution.* Dissolve an accurately weighed portion of the cefoxitin working standard with water to obtain a solution containing 200 micrograms of cefoxitin per milliliter.

(ii) *Sample solution.* Using a suitable hypodermic needle and syringe, remove an accurately measured representative portion from each container and dilute with sufficient water to obtain a solution containing 200 micrograms of cefoxitin per milliliter (estimated).

(iii) *Calculations.* Calculate the milligrams of cefoxitin per milliliter of sample as follows:

$$\text{Milligrams of cefoxitin per milliliter} = \frac{A_u \times P_s \times d}{A_s \times 1,000}$$

where:

A_u =Area of the cefoxitin peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s =Area of the cefoxitin peak in the chromatogram of the cefoxitin working standard;

P_s =Cefoxitin activity in the cefoxitin 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.

(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 cefoxitin per kilogram.

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

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

[49 FR 47827, Dec. 7, 1984, as amended at 55 FR 11583, Mar. 29, 1990]