

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

P_s =Cefpiramide activity in the cefpiramide 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 § 436.20(e)(1).

(3) *Pyrogens*. Proceed as directed in § 436.32(b) of this chapter, using a solution containing 50 milligrams of cefpiramide 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 an aqueous solution containing 100 milligrams per milliliter.

(6) *Identify*. The high-performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the cefpiramide working standard.

[55 FR 14242, Apr. 17, 1990]

§ 442.270 Cefmetazole injectable dosage forms.

§ 442.270a Sterile cefmetazole sodium.

The requirements for certification and the tests and methods of assay for sterile cefmetazole sodium packaged for dispensing are described in § 442.70a.

[55 FR 6636, Feb. 26, 1990]

§ 442.270b Cefmetazole sodium injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Cefmetazole sodium injection is a frozen, aqueous, iso-osmotic solution of cefmetazole and sodium citrate. It contains one or more suitable and harmless buffer substances and a tonicity adjusting agent. Each milliliter contains cefmetazole sodium equivalent to 20 milligrams or 40 milligrams of cefmetazole per milliliter. Its cefmetazole content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefmetazole that it is represented to contain. It is sterile. It contains not more than 0.2 endotoxin units per milligram. Its pH is not less than 4.2 and not more than 6.2. It

passes the identity test. The cefmetazole used conforms to the standards prescribed by § 442.69(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 cefmetazole used in making the batch for potency, moisture, and identity.

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

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

(A) The cefmetazole 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.

(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) *Cefmetazole potency*. Proceed as directed in § 442.70a(b)(1), except prepare the sample solution and calculate the cefmetazole content as follows:

(i) *Preparation of sample solution*. Using a suitable hypodermic needle and syringe, remove an accurately measured portion from each container immediately after thawing and reaching room temperature and dilute with mobile phase to obtain a solution containing 500 micrograms of cefmetazole per milliliter (estimated). Prepare the sample solution just prior to its introduction into the chromatograph.

(ii) *Calculation*. Calculate the milligrams of cefmetazole per milliliter of sample as follows:

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

where:

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