

§ 442.225b Cephalothin sodium injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cephalothin sodium injection is a frozen aqueous solution of cephalothin sodium with one or more suitable and harmless buffer substances. It may contain sodium chloride or dextrose. Each milliliter contains cephalothin sodium equivalent to 20 milligrams, 40 milligrams, or 100 milligrams of cephalothin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of cephalothin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 6.0 and not more than 8.5. The cephalothin sodium used conforms to the standards prescribed by § 442.25a(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 cephalothin sodium used in making the batch for potency, loss on drying, pH, specific rotation, identity, and crystallinity.

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

(ii) Samples required:

(a) The cephalothin 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 ampoule contents 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 microbiological agar diffusion 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 1.0 microgram of cephalothin 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(b) of this chapter, using a solution containing 50 milligrams of cephalothin per milliliter.

(4) [Reserved]

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

[40 FR 11351, Mar. 11, 1975, as amended at 49 FR 13493, Apr. 5, 1984; 50 FR 19919, May 13, 1985]

§ 442.225c Cephalothin sodium for injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cephalothin sodium for injection is a dry mixture of cephalothin sodium with one or more suitable and harmless buffer substances. The cephalothin sodium may be isolated in the manufacture of cephalothin sodium for injection. Its cephalothin content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of cephalothin that it is represented to contain. It is sterile. It is nonpyrogenic. Its loss on drying is not more than 1.5 percent. When reconstituted as directed in the labeling, its pH is not less than 6.0 and not more than