

aseptically transfer approximately 300 milligrams of sample into a sterile 500-milliliter Erlenmeyer flask containing approximately 400 milliliters of diluting fluid D. Add at least 200,000 Levy units¹ of penicillinase. Repeat the process using 10 additional containers. Swirl both of the stoppered flasks to completely solubilize the suspension prior to filtration and proceed as directed in paragraph (e)(1)(ii) of that section. If the formulation cannot be filtered, proceed as directed in § 436.20(e)(2) of this chapter, except use medium B in lieu of medium A.

(3) *Pyrogens*. Proceed as directed in § 436.32(f) of this chapter, using a solution containing 20 milligrams of ampicillin per milliliter.

(4) [Reserved]

(5) *Loss on drying*. Proceed as directed in § 436.200(a) of this chapter.

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

[39 FR 18976, May 30, 1974, as amended at 49 FR 3459, Jan. 27, 1984; 50 FR 19918, 19919, May 13, 1985]

§ 440.209 Ampicillin sodium injectable dosage forms.

§ 440.209a Sterile ampicillin sodium.

The requirements for certification and the tests and methods of assay for sterile ampicillin sodium packaged for dispensing are described in § 440.9a.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59867, Nov. 22, 1977. Redesignated at 52 FR 42288, Nov. 4, 1987]

§ 440.209b Sterile ampicillin sodium and sulbactam sodium.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Ampicillin sodium and sulbactam sodium is a dry mixture of ampicillin sodium and sulbactam sodium in which the ratio of ampicillin to sulbactam is 2:1. Its ampicillin potency is not less than 563 micrograms of ampicillin per milligram on an an-

¹One Levy unit of penicillinase inactivates 59.3 units of penicillin G in 1 hour at 25° C. and at a pH of 7.0 in a phosphate buffered solution of a pure alkali salt of penicillin G when the substrate is in sufficient concentration to maintain a zero order reaction.

hydrous basis. It contains not less than 280 micrograms of sulbactam per milligram on an anhydrous basis. Its ampicillin sodium content is satisfactory if it contains not less than 90 percent and not more than 115 percent of the number of milligrams of ampicillin that it is represented to contain. Its sulbactam sodium content is satisfactory if it contains not less than 90 percent and not more than 115 percent of the number of milligrams of sulbactam that it is represented to contain. It is sterile. It is nonpyrogenic. Its moisture content is not more than 2.0 percent. The pH of an aqueous solution containing 10 milligrams of ampicillin and 5 milligrams of sulbactam per milliliter is not less than 8.0 and not more than 10.0. It passes the identity test for ampicillin and sulbactam. The ampicillin sodium content conforms to the standards prescribed by § 440.9a(a)(1) of this chapter. The sulbactam content conforms to the standards prescribed by § 455.82a(a)(1) of this chapter.

(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 the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The ampicillin sodium used in making the batch for potency, sterility, pyrogens, moisture, pH, crystallinity, and identity.

(B) The sulbactam sodium used in making the batch for potency, sterility, pyrogens, moisture, crystallinity, and identity.

(C) The batch for ampicillin potency, sulbactam potency, sterility, pyrogens, moisture, pH, and identity.

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

(A) The ampicillin sodium used in making the batch: 12 packages, each containing approximately 300 milligrams.

(B) The sulbactam sodium used in making the batch: 12 packages, each containing approximately 300 milligrams.

(C) The batch:

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