

colorimetric assay, to give a stock solution of convenient concentration.

(ii) *Assay procedure.* Use any of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 5 micrograms of dicloxacillin per milliliter (estimated).

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with distilled water to the prescribed concentration.

(c) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter, except dilute an aliquot of the stock solution 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, using a solution containing 20 milligrams of dicloxacillin per milliliter.

(4) [Reserved]

(5) *Moisture.* Proceed as directed in § 436.201 of this chapter.

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

[39 FR 18976, May 30, 1974, as amended at 42 FR 59867, Nov. 22, 1977; 50 FR 19918, 19919, May 13, 1985]

§ 440.229 Hetacillin potassium injectable dosage forms.

§ 440.229a Sterile hetacillin potassium.

The requirements for certification and the tests and methods of assay for sterile hetacillin potassium packaged for dispensing are described in § 440.29a.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59867, Nov. 22, 1977]

§ 440.229b Hetacillin potassium for injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Hetacillin potassium for injection is a dry mixture of hetacillin

potassium and lidocaine hydrochloride. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. It is sterile and nonpyrogenic. Its moisture content is not more than 1.0 percent. When reconstituted as directed in its labeling, its pH is not less than 7.0 and not more than 9.0. The hetacillin potassium used conforms to the requirements of § 440.29a(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 hetacillin potassium used in making the batch for potency, moisture, pH, hetacillin content, identity, and crystallinity.

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

(ii) Samples required:

(a) The hetacillin potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers, except if each contains less than 450 milligrams of ampicillin, a minimum of 16 immediate containers.

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

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed for ampicillin in § 436.105 of this chapter, using the ampicillin working standard as the standard of comparison and preparing the sample for assay as follows: Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove the withdrawable contents from each container represented as a single-dose container; or, if the labeling specifies the amount of potency in a given volume of the resultant preparation, withdraw an accurately measured representative portion from each container. Dilute the sample thus obtained with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution