

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

[39 FR 18976, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 440.125b Hetacillin for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Hetacillin for oral suspension is a mixture of hetacillin with one or more suitable preservatives, suspending agents, sweetening ingredients, flavorings, and colorings. When reconstituted as directed in the labeling, it contains the equivalent of 22.5, 45, or 112.5 milligrams of ampicillin per milliliter. 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. Its moisture content is not more than 2.0 percent. The pH of the suspension, when reconstituted as directed in its labeling, is not less than 2.0 and not more than 5.0. The hetacillin used conforms to the requirements of § 440.25(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 used in making the batch for potency, moisture, pH, hetacillin content, identity, and crystallinity.

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

(ii) Samples required:

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

(b) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay—(1) Potency*. Proceed as directed for ampicillin in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the sample as directed in the labeling. Remove an accurately measured representative portion with a suitable syringe and hypodermic needle and place into a suitable volumetric flask. Dilute to volume with 0.1M potassium phosphate buffer, pH 8.0 (solu-

tion 3). Further dilute an aliquot with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

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

(3) *pH*. Proceed as directed in § 436.202 of this chapter, using the sample after reconstituting as directed in the labeling.

[39 FR 18976, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 440.129 Hetacillin potassium capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Hetacillin potassium capsules are composed of potassium hetacillin with or without one or more suitable diluents, lubricants, and drying agents. Each capsule contains an amount of potassium hetacillin equivalent to 112.5, 225, or 450 milligrams of ampicillin. 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. The moisture content is not more than 3 percent. The potassium hetacillin used conforms to the requirements of § 440.29(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 and moisture.

(ii) Samples required:

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

(b) The batch: A minimum of 30 capsules.

(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