

(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

the sample for assay as follows: Place a representative number of capsules in a high-speed glass blender with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution 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.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59861, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

**§ 440.141 Nafcillin sodium monohydrate oral dosage forms.**

**§ 440.141a Nafcillin sodium monohydrate tablets.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Nafcillin sodium monohydrate tablets are composed of nafcillin sodium monohydrate with one or more suitable buffers, binders, disintegrants, diluents, and lubricants. Each tablet contains nafcillin sodium monohydrate equivalent to 500 milligrams of nafcillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of nafcillin that it is represented to contain. Its moisture content is not more than 5 percent. It shall disintegrate within 20 minutes. The nafcillin sodium monohydrate used conforms to the standards prescribed by § 440.41(a)(1).

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled "nafcillin sodium tablets".

(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 nafcillin sodium monohydrate used in making the batch for potency, moisture, pH, crystallinity, nafcillin content, and identity.

(b) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(a) The nafcillin sodium monohydrate used in making the

batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay—(1) Potency—(i) Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Assay for potency by 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 2.0 micrograms of nafcillin per milliliter (estimated).

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(c) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter.

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

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the method described in paragraph (e)(1) of that section, except use distilled water in lieu of simulated gastric fluid as the immersion fluid.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59862, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

**§ 440.141b Nafcillin sodium monohydrate capsules.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Nafcillin sodium monohydrate capsules are composed of nafcillin sodium monohydrate and one or more suitable and harmless buffer substances and lubricants. Each capsule contains nafcillin sodium monohydrate equivalent to 250 milligrams of nafcillin. The potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of nafcillin