

than 125 percent of the number of milligrams of ampicillin that it is represented to contain. Its moisture content is not more than 2.5 percent. It passes the dissolution test. The bacampicillin hydrochloride used conforms to the standards prescribed by § 440.8(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 bacampicillin hydrochloride used in making the batch for potency, moisture, pH, and identity.

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

(ii) Samples required:

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

(b) The batch: A minimum of 100 tablets.

(b) *Tests and methods of assay—(1) Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Hydroxylamine colorimetric assay.* Proceed as directed in § 440.8(b)(1)(i) of this chapter, except prepare the sample solution and calculate the potency of the sample as follows:

(a) *Preparation of sample solution.* Place one tablet into a high-speed glass blender jar with sufficient distilled water to obtain a concentration of 1.25 milligrams of ampicillin per milliliter (estimated). Blend for 3 to 5 minutes. Filter before using.

(b) *Calculations.* Calculate the ampicillin content in milligrams per tablet as follows:

$$\text{Milligrams of ampicillin per tablet} = \frac{A_u \times P_a \times d}{A_s \times 1,000}$$

where:

A_u =Absorbance of sample solution;

P_a =Potency of working standard in micrograms per milliliter;

A_s =Absorbance of working standard solution;

d =Dilution factor of the sample.

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, except use the ampicillin working standard. Prepare the sample as follows: Dissolve and dilute a representative number of tablets with distilled water to the prescribed concentration.

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

(3) *Dissolution.* Proceed as directed in § 436.215 of this chapter, except in lieu of paragraph (d) of that section use the interpretation described in the United States Pharmacopeia XX dissolution test. The quantity, Q (the amount of ampicillin dissolved) is 85 percent at 30 minutes.

[46 FR 25604, May 8, 1981. Redesignated at 47 FR 23711, June 1, 1982, and amended at 48 FR 51293, 51294, Nov. 8, 1983; 50 FR 19919, May 13, 1985]

§ 440.108b Bacampicillin hydrochloride for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Bacampicillin hydrochloride for oral suspension is a mixture of bacampicillin hydrochloride with one or more suitable and harmless buffers, diluents, sweetening ingredients, suspending agents, flavorings, and colorings. When reconstituted as directed in the labeling, it contains bacampicillin hydrochloride equivalent to 17.5 milligrams of ampicillin per milliliter. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of ampicillin that it is represented to contain. Its loss on drying is not more than 2.0 percent. When reconstituted as directed in the labeling, its pH is not less than 6.5 and not more than 8.0. It gives a positive identity test for bacampicillin hydrochloride. The bacampicillin hydrochloride conforms to the standards prescribed by § 440.8(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 bacampicillin used in making the batch for potency, moisture, pH, and identity.

(b) The batch for potency, loss on drying, pH, and identity.

(ii) Samples required:

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

(b) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.204 of this chapter, except:

(i) Use the ampicillin working standard as the standard of comparison;

(ii) Use 4.0 milliliters of sample solution in lieu of the 2.0 milliliters specified in paragraph (c)(1) of that section; and

(iii) Calculate the potency of the sample as follows:

$$\text{Milligrams of ampicillin per dose} = \frac{V_u \times F \times d}{n \times 4,000}$$

Prepare the sample as follows: Reconstitute the drug as directed in the labeling. Place an accurately measured portion equivalent to one dose into a 250-milliliter volumetric flask. Add 200 milliliters of a solvent mixture of 95 percent ethanol and 0.1M phosphoric acid (8:2). Shake for 30 minutes on a wrist action shaker and dilute to volume with the solvent mixture. Centrifuge a portion of the sample solution for 10 minutes at 6,000 rpm. Use the clear supernatant without further dilution.

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

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

(4) *Identity*. Proceed as directed in § 436.330 of this chapter, except prepare the sample as follows: Reconstitute as directed in the labeling. Place 8.0 milliliters of the sample into a 100-milliliter volumetric flask, add 70 milliliters of 95 percent ethyl alcohol and shake for 30 minutes. Dilute to volume with 95 percent ethyl alcohol.

[47 FR 23711, June 1, 1982, as amended at 50 FR 19919, May 13, 1985]

§ 440.111 Carbenicillin indanyl sodium tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Carbenicillin indanyl sodium tablets are composed of carbenicillin indanyl sodium and one or more suitable and harmless diluents, binders, lubricants, colorings, and coating substances. Each tablet contains carbenicillin indanyl sodium equivalent to 382 milligrams of carbenicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of carbenicillin that it is represented to contain. Its moisture content is not more than 2.0 percent. It gives a positive identity test for carbenicillin indanyl sodium. The tablets shall disintegrate within 1 hour. The carbenicillin indanyl sodium used conforms to the standards prescribed by § 440.11(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 carbenicillin indanyl sodium used in making the batch for potency, moisture, pH, and identity.

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

(ii) Samples required:

(a) The carbenicillin indanyl sodium used in making the batch: Five packages, each containing approximately 1 gram and one package containing approximately 2.5 grams.

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

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.300 of this chapter, except:

(i) *Preparation of the sample*. Accurately weigh 20 tablets and determine the average tablet weight. Using a mortar and pestle, grind the tablets to a fine powder. Accurately weigh a portion of the powder approximately equivalent to the weight of one tablet and transfer it into a 100-milliliter volumetric flask. Add approximately 70 milliliters of distilled water and shake