

follows: Reconstitute the drug as directed in the labeling. Place an accurately measured aliquot (usually a single dose) into an appropriately sized volumetric flask and dilute to volume with distilled water. Mix well. Further dilute with distilled water to the prescribed concentration.

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

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

[39 FR 18976, May 30, 1974, as amended at 49 FR 3458, Jan. 27, 1984; 50 FR 19919, May 13, 1985]

§ 440.107 Ampicillin trihydrate oral dosage forms.

§ 440.107a Ampicillin trihydrate chewable tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Ampicillin trihydrate chewable tablets are composed of ampicillin trihydrate with or without one or more suitable diluents, lubricants, preservatives, and flavorings. Each tablet contains ampicillin trihydrate equivalent to 125 or 250 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. Its moisture content is not more than 5.0 percent. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled “ampicillin 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 ampicillin trihydrate used in making the batch for potency, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The ampicillin trihydrate used in making the batch: 10 packages, each

containing approximately 300 milligrams.

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

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

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar 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. Remove an aliquot and further dilute with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, except in paragraph (d) of that section, add 3 drops of 1.2N hydrochloric acid to both the sample and working standard solutions after the addition of 0.01N iodine solution. Prepare the sample as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient distilled water to give a convenient concentration. Blend for 5 minutes. Further dilute with distilled water to the prescribed concentration.

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

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

§ 440.107b Ampicillin trihydrate capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Ampicillin trihydrate capsules are composed of ampicillin trihydrate with or without one or more buffer substances, diluents, binders, lubricants, vegetable oils, colorings, and flavorings enclosed in a gelatin capsule. Each capsule contains ampicillin trihydrate equivalent to 250 milligrams or 500 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. Its loss on drying is not less than 10 percent and not more than 15 percent. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled "ampicillin capsules".

(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 ampicillin trihydrate used in making the batch for potency, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

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

(ii) Samples required:

(a) The ampicillin trihydrate 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.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, except in paragraph (d) of that section, add 3 drops of 1.2N hydrochloric acid to both the sample and working standard solutions after the addition of 0.01N iodine solution. Prepare the sample as follows: Place the contents of a representative number of capsules into a high-speed glass blender jar and add sufficient distilled water to give a con-

venient concentration. Blend for 3 to 5 minutes. Filter through Whatman No. 2 filter paper. Further dilute an aliquot of the filtrate with distilled water to the prescribed concentration.

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

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

§ 440.107c Ampicillin trihydrate for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Ampicillin trihydrate for oral suspension is a mixture of ampicillin trihydrate with one or more suitable and harmless colorings, flavorings, buffers, sweetening ingredients, and preservatives. When reconstituted as directed in the labeling, it contains ampicillin trihydrate equivalent to either 25, 50, or 100 milligrams of ampicillin per milliliter. Its potency is satisfactory if it is 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:

(i) Not more than 2.5 percent if it contains sugar and is intended to contain the equivalent of 25 or 50 milligrams of ampicillin per milliliter when reconstituted as directed in the labeling; or

(ii) Not more than 5 percent if it contains sugar and is intended to contain the equivalent of 100 milligrams of ampicillin per milliliter when reconstituted as directed in the labeling; or

Its pH, when reconstituted as directed in the labeling, is not less than 5.0 and is not more than 7.5. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled "ampicillin for oral suspension."

(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 ampicillin trihydrate used in making the batch for potency, loss on