

## Subpart B—Oral Dosage Forms

**§ 440.103 Amoxicillin oral dosage forms.****§ 440.103a Amoxicillin trihydrate capsules.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate capsules are composed of amoxicillin trihydrate with or without one or more suitable and harmless lubricants, diluents, and drying agents, enclosed in a gelatin capsule. Each capsule contains amoxicillin trihydrate equivalent to 250 milligrams or 500 milligrams of amoxicillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of amoxicillin that it is represented to contain. Its moisture content is not more than 14.5 percent. It passes the identity test. The amoxicillin trihydrate used conforms to the standards prescribed by § 440.3(a)(1).

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

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

(ii) Samples required:

(a) The amoxicillin trihydrate used in making the batch: 12 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 iodometric 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 containing 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 amoxicillin 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 convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot with distilled water to the prescribed concentration.

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

(3) *Identity.* Proceed as directed in § 436.311 of this chapter, preparing the sample solution as follows: Dissolve an accurately weighed portion of the amoxicillin capsule contents in 0.1N hydrochloric acid to give a solution containing 4 milligrams of amoxicillin per milliliter.

[39 FR 34033, Sept. 23, 1974, as amended at 49 FR 3458, Jan. 27, 1984; 50 FR 19919, May 13, 1985]

**§ 440.103b Amoxicillin trihydrate for oral suspension.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate for oral suspension is a mixture of amoxicillin trihydrate with one or more suitable and harmless colorings, flavorings, buffers, sweetening ingredients, preservatives, stabilizers, and suspending agents. When reconstituted as directed in the labeling, it contains amoxicillin trihydrate equivalent to either 25 or 50 milligrams of amoxicillin 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 amoxicillin that it is represented to contain. Its moisture content is not more than 3.0 percent. Its pH, when reconstituted as directed

in the labeling, is not less than 5.0 and not more than 7.5. It passes the identity test. The amoxicillin trihydrate used conforms to the standards prescribed by § 440.3(a)(1).

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

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

(ii) Samples required:

(a) The amoxicillin trihydrate used in making the batch: 12 packages, each containing approximately 300 milligrams.

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

(b) *Tests and methods of assay*—(1) *Potency.* Assay for potency by either of the following methods; however, the results obtained from the iodometric 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: Reconstitute the drug as directed in the labeling. Place an accurately measured representative portion of the sample into a suitable volumetric flask and dilute to volume with 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Mix well. Further dilute an aliquot with solution 3 to the reference concentration of 0.1 microgram of amoxicillin 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: 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 suspension reconstituted as directed in the labeling.

(4) *Identity.* Proceed as directed in § 436.311 of this chapter, preparing the sample solution as follows: From an aliquot of suspension prepared in accordance with the label, make either a 6.25:1 dilution for the 25-milligrams-per-milliliter dosage; or a 12.5:1 dilution for the 50-milligrams-per-milliliter dosage, with 0.1N hydrochloric acid. The slight dilution of the acid does not have a significant effect on the test.

[39 FR 34033, Sept. 23, 1974, as amended at 49 FR 3458, Jan. 27, 1984; 50 FR 19919, May 13, 1985; 54 FR 47351, Nov. 14, 1989]

#### § 440.103c Amoxicillin trihydrate chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate chewable tablets are composed of amoxicillin trihydrate with or without one or more suitable lubricants, diluents, preservatives, drying agents, flavorings, and colorings. Each tablet contains amoxicillin trihydrate equivalent to either 125 or 250 milligrams of amoxicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of amoxicillin that it is represented to contain. Its moisture content is not more than 6.0 percent. It passes the identity test. The amoxicillin trihydrate used conforms to the standards prescribed by § 440.3(a)(1).

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

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assay on: