

**Subpart B—Oral Dosage Forms**

**§ 449.104 Amphotericin B oral suspension.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Amphotericin B oral suspension is a mixture of amphotericin B with one or more suitable and harmless preservatives, colorings, sweetening ingredients, flavorings, buffer substances, lubricants, suspending agents, and sequestrants in an aqueous vehicle. Each milliliter contains 100 milligrams of amphotericin B. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of amphotericin B that it is represented to contain. Its pH is not less than 4.5 and not more than 6.0. The amphotericin B conforms to the standards prescribed by § 449.4(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 amphotericin B used in making the batch for potency, amphotericin A content, loss on drying, pH, residue on ignition, and identity.

(b) The batch for potency and pH.

(ii) Samples required:

(a) The amphotericin B used in making the batch: 10 packages, each containing approximately 500 milligrams.

(b) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately measured representative portion into a high-speed glass blender with sufficient dimethylsulfoxide to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with dimethylsulfoxide to give a concentration of 20 micrograms of amphotericin B per milliliter (estimated). Further dilute an aliquot with 0.2M potassium phosphate buffer, pH 10.5 (solution 10), to the reference concentration of 1.0

microgram of amphotericin B per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted suspension.

[39 FR 19134, May 30, 1974, as amended at 50 FR 19920, May 13, 1985]

**§ 449.120 Griseofulvin oral dosage forms.**

**§ 449.120a Griseofulvin tablets.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Griseofulvin tablets are tablets composed of griseofulvin, with or without one or more suitable fillers, colorings, lubricants, and binders. Each tablet contains 125, 250, or 500 milligrams of griseofulvin. The griseofulvin content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of griseofulvin that it is represented to contain. The loss on drying is not more than 5.0 percent. The tablets shall disintegrate within 1 hour. The griseofulvin used conforms to the standards prescribed by § 449.20(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 the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The griseofulvin used in making the batch for griseofulvin content, loss on drying, melting point, specific rotation, identity, residue on ignition, heavy metals, specific surface area, and crystallinity.

(b) The batch for griseofulvin content, loss on drying, and disintegration time.

(ii) Samples required:

(a) The griseofulvin used in making the batch: 10 packages, each containing not less than 1 gram.

(b) The batch for griseofulvin content, loss on drying, and disintegration time.

(b) *Tests and methods of assay—(1) Griseofulvin content (gas liquid chromatography).* Proceed as directed in § 436.321 of this chapter, except:

(i) Prepare the sample solution as follows: Accurately weigh 20 tablets