

(9) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

[39 FR 19149, May 30, 1974, as amended at 48 FR 3960, Jan. 28, 1983; 50 FR 19920, 19921, May 13, 1985]

Subpart B—Oral Dosage Forms

§ 452.110 Erythromycin oral dosage forms.

§ 452.110a Erythromycin tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Erythromycin tablets are erythromycin with suitable and harmless buffer substances, diluents, binders, lubricants, colorings, flavorings, and suitable preservatives. The potency of each tablet is 250 milligrams or 500 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of erythromycin that it is represented to contain. Tablets shall disintegrate within 1 hour. The loss on drying is not more than 5.0 percent. The erythromycin used in making the batch conforms to the standards prescribed by § 452.10(a)(1), except heavy metals.

(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 erythromycin used in making the batch for potency, pH, moisture, residue on ignition, crystallinity, and identity.

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

(ii) Samples required:

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

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

(b) *Tests and methods of assay—(1) Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend a representative number of tablets in a high-speed glass blender for 2 to 3 minutes with 200 milliliters of methyl alcohol. Add 300 milliliters of 0.1M potassium phos-

phate buffer, pH 8.0 (solution 3), and blend again for 2 to 3 minutes. Further dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

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

(3) *Disintegration time*. Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(2) of that section.

[39 FR 19149, May 30, 1974, as amended at 42 FR 59068, Nov. 15, 1977; 50 FR 19921, May 13, 1985]

§ 452.110b Erythromycin enteric-coated tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Erythromycin enteric-coated tablets are enteric-coated tablets composed of erythromycin, suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains 100, 250, 333, or 500 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of erythromycin that it is represented to contain. The tablets shall disintegrate within 2 hours. The moisture content is not more than 6 percent. The erythromycin base used in making the batch conforms to the standards of § 452.10(a)(1) (i), (iii), (iv), (v), (vii), and (viii).

(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 erythromycin used in making the batch for potency, moisture, pH, residue on ignition, crystallinity, and identity.

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

(ii) Samples required:

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

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