(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 0.1*M* potassium phosphate 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) *Moisture.* Proceed as directed in §436.201 of this chapter.

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

[39 FR 14149, May 30, 1974, as amended at 44 FR 30332, May 25, 1979; 44 FR 48190, Aug. 17, 1979; 46 FR 44442, Sept. 4, 1981; 47 FR 15326, Apr. 9, 1982; 50 FR 19921, May 13, 1985]

§452.110c Erythromycin capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin capsules are capsules containing enteric-coated erythromycin pellets, suitable and harmless buffer substances, diluents, binders, lubricants, and colorings. Each capsule contains either 125 milligrams or 250 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of erythromycin that it is represented to contain. The moisture content is not more than 7.5 percent. It passes the acid resistance/dissolution test. The erythromycin used 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 complying with 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, identity, and crystallinity.

(*b*) The batch for potency, moisture, and acid resistance/dissolution.

(ii) Samples required:

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

(*b*) The batch: A minimum of 100 capsules.

(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 a representative number of capsules into a high-speed glass blender jar containing 200 milliliters of methyl alcohol. Blend for 2 to 3 minutes. Add 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 2 to 3 minutes. Further dilute an aliquot with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter, using the sample preparation method described in paragraph (d)(1) of that section.

(3) *Acid resistance/dissolution.* Proceed as directed in §436.542 of this chapter. The quantity Q (the amount of erythromycin dissolved) is 85 percent at 45 minutes.

[46 FR 16678, Mar. 13, 1981; 46 FR 22359, Apr. 17, 1981, as amended at 50 FR 19921, May 13, 1985; 50 FR 36992, Sept. 11, 1985; 50 FR 47214, Nov. 15, 1985]

§452.110d Erythromycin particles in tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin particles in tablets are tablets containing erythromycin acid-resistant coated particles, suitable and harmless diluents, binders, lubricants, and colorings. Each tablet contains 333 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 loss on drying is not more than 5.0 percent. It passes the dissolution test and the acid resistance test. The erythromycin used 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 complying with 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, safety, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency, loss on drying, dissolution, and acid resistance.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

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

(*b*) The batch: A minimum of 100 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: Place a representative number of tablets into a high-speed glass blender jar containing 200 milliliters of methyl alcohol. Blend for 2 to 3 minutes. Add 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 2 to 3 minutes. Further dilute an aliquot 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) *Dissolution.* Proceed as directed in § 436.215 of this chapter. The quantity *Q* (the amount of erythromycin dissolved) is 75 percent at 45 minutes.

(4) *Acid resistance.* Proceed as directed in § 436.545 of this chapter. The quantity of erythromycin dissolved is not more than 25 percent at 60 minutes.

[51 FR 37723, Oct. 24, 1986, as amended at 55 FR 11584, Mar. 29, 1990]

§ 452.115 Erythromycin estolate oral dosage forms.

§ 452.115a Erythromycin estolate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin estolate tablets are composed of erythromycin estolate with one or more suitable and harmless diluents, binders, lubricants, and colorings. Each tablet contains erythromycin estolate equivalent to 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 moisture content is not more than 5 percent. The tablets shall disintegrate within 30 minutes. The erythromycin estolate used conforms to the standards prescribed by § 452.15(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 erythromycin estolate used in making the batch for potency, moisture, pH, identity, and crystallinity.

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

(ii) Samples required:

(*a*) The erythromycin estolate used in making the batch: 10 packages, each containing approximately 300 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: Place a representative number of tables into a high-speed glass blender jar with 200 milliliters of methyl alcohol. Blend for 3 to 5 minutes. Add 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 3 to 5 minutes. Hydrolyze a portion of this solution in a 60° C. constant temperature water bath for 2 hours or at room temperature for 16 to 18 hours. Further dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

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

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(1) of that section.

[39 FR 19149, May 30, 1974, as amended at 50 FR 19921, May 13, 1985]