

**§ 452.115b Erythromycin estolate capsules.**

(a) *Requirements for certification—(1) Standards of identity, quality, and purity.* Erythromycin estolate capsules are capsules containing erythromycin estolate with suitable and harmless buffer substances and diluents enclosed in a gelatin capsule. The erythromycin estolate content of each capsule is equivalent to either 250 milligrams of erythromycin or 125 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 5 percent. The erythromycin estolate used conforms to the standards prescribed therefor 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 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, pH, moisture, crystallinity, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The erythromycin estolate used in making the batch: 10 packages, each containing not less than 300 milligrams.

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

(b) *Test 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 capsules in a high-speed glass blender with 200 milliliters of methyl alcohol for 2 to 3 minutes. Add 300 milliliters of 0.1M potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 2 to 3 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.

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

**§ 452.115c Erythromycin estolate oral suspension.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Erythromycin estolate oral suspension is erythromycin estolate with suitable and harmless buffer substances, dispersing agents, diluents, coloring, and flavorings. Each milliliter contains erythromycin estolate equivalent to 25, 50, or 100 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. Its pH is not less than 3.5 and not more than 6.5. The erythromycin estolate used conforms to the standards prescribed by § 452.15(a)(1).

(2) *Labeling.* In addition to conforming with the requirements of § 432.5 of this chapter, each package shall bear on its outside wrapper or container and the immediate container the statement "Refrigerate" or "Keep under refrigeration".

(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 estolate used in making the batch for potency, moisture, pH, crystallinity, and identity.

(b) The batch for potency and pH.

(ii) Samples required:

(a) The erythromycin estolate used in making the batch: 10 containers, each having not less than 300 milligrams.

(b) The batch: A minimum of six 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: Remove an accurately measured representative volume of the suspension and dilute with sufficient methyl alcohol to give a concentration of 2.5 milligrams per milliliter (estimated). Dilute the entire mixture with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a

concentration of 1.0 milligram of erythromycin base per milliliter (estimated). Hydrolyze 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) *pH*. Proceed as directed in § 436.202 of this chapter, using the drug as it is prepared for dispensing.

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

**§ 452.115d Erythromycin estolate for oral suspension.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Erythromycin estolate for oral suspension is a dry mixture of erythromycin estolate with suitable and harmless buffer substances, dispersing agents, diluents, colorings, and flavorings. The erythromycin estolate content is 25 milligrams of erythromycin per milliliter of the reconstituted suspension. 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. When reconstituted as directed in its labeling, its pH is not less than 5.0 and not more than 7.0. Its moisture content is not more than 2.0 percent. The erythromycin estolate used conforms to the standards of § 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 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, crystallinity, and identity.

(b) The batch: Potency, moisture, and pH.

(ii) Samples required:

(a) The erythromycin estolate used in making the batch: 10 immediate containers, each consisting of 300 milligrams.

(b) The batch: A minimum of 6 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: Reconstitute the sample as directed in the labeling. Withdraw an accurately measured representative volume of the reconstituted suspension and add sufficient methyl alcohol to give a concentration of 2.5 milligrams of erythromycin base per milliliter (estimated). Dilute this entire mixture with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a concentration of 1.0 milligram of erythromycin base per milliliter (estimated). Hydrolyze 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, using the dry powder.

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

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

**§ 452.115e Erythromycin estolate for pediatric drops.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Erythromycin estolate for pediatric drops is a dry mixture of erythromycin estolate with suitable and harmless dispersing agents, buffer substances, diluents, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains the equivalent of 100 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. Its moisture content is not more than 2.0 percent. Its pH is not less than 5.0 nor more than 5.5. 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 the requirements of