

(a) The troleandomycin used in making the batch: 10 packages, nine containing approximately 500 milligrams each and one containing approximately 2 grams.

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

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar with sufficient 80 percent isopropyl alcohol solution (solution 15) to obtain a stock solution containing 1,000 micrograms of troleandomycin per milliliter (estimated). Blend 3 to 5 minutes. Further dilute an aliquot of the stock solution with distilled water to the reference concentration of 25 micrograms of troleandomycin per milliliter (estimated).

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

[39 FR 19149, May 30, 1974, as amended at 48 FR 3960, Jan. 28, 1983; 48 FR 36571, Aug. 12, 1983; 50 FR 19921, May 13, 1985]

Subpart C—Injectable Dosage Forms

§ 452.225 Erythromycin ethylsuccinate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin ethylsuccinate injection is erythromycin ethylsuccinate and butylaminobenzoate dissolved in polyethylene glycol 400. It contains a suitable and harmless preservative. Each milliliter contains 50 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. It contains 2 percent butylaminobenzoate. It is sterile. Its moisture content is not more than 1.5 percent. The erythromycin ethylsuccinate used conforms to the standards prescribed therefore by § 452.25a(a)(1).

(2) *Labeling*. In addition to the labeling requirements prescribed by § 432.5 of this chapter, each immediate container shall bear on its label and label-

ing the statement: “Warning—For intramuscular use only”.

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

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

(ii) Samples required:

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

(b) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation, except that if the product is sterilized after filling, a representative sample consisting of 10 immediate containers from each sterilizer load. If only one sterilizer load is involved, the sample shall consist of 20 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: By means of a suitable hypodermic needle and syringe, remove an accurately measured representative volume of the sample and dilute with sufficient methyl alcohol to give a solution containing 1.0 milligram of erythromycin base per milliliter (estimated). Further dilute with 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except use a bacterial-retentive membrane resistant to the solvent polyethylene glycol 400 and add 1 milliliter from each immediate container directly to the membrane, thus eliminating the preliminary solubilization step.

(3) [Reserved]

(4) *Moisture*. Proceed as directed in § 436.201(e)(1) of this chapter.

[39 FR 19149, May 30, 1974, as amended at 50 FR 19920, 19921, May 13, 1985]

§ 452.230 Sterile erythromycin gluceptate.

The requirements for certification and the tests and methods of assay for sterile erythromycin gluceptate packaged for dispensing are described in § 452.30a.

[46 FR 16685, Mar. 13, 1981]

§ 452.232 Erythromycin lactobionate injectable dosage forms.

§ 452.232a Erythromycin lactobionate for injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Erythromycin lactobionate for injection is a dry mixture of erythromycin lactobionate and a suitable preservative. It contains the equivalent of 300 milligrams, 500 milligrams, or 1 gram of erythromycin per vial. 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. It is sterile. It is nonpyrogenic. Its moisture content is not more than 5 percent. Its pH is not less than 6.5 and not more than 7.5. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1) (i), (iii), (iv), (v), (vi), (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, pH, moisture, residue on ignition, heavy metals, and crystallinity.

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

(ii) Samples required:

(a) The erythromycin used in making the batch: 10 containers, each consisting of not less than 500 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 12 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(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 as directed in the labeling. Using a suitable hypodermic needle and syringe, remove the total withdrawable contents from each container represented as a single-dose container; or if the labeling specifies the amount of potency in a given volume of the preparation, withdraw an accurately measured volume from each container. Dilute with sterile distilled water to obtain a concentration of 10 milligrams of erythromycin base per milliliter (estimated). Further dilute with 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 30 milligrams of erythromycin per milliliter.

(4) [Reserved]

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

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using a concentration of 50 milligrams of erythromycin per milliliter.

(7) *Identity.* Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(2) of that section.

[39 FR 19149, May 30, 1974, as amended at 50 FR 19920, 19921, May 13, 1985. Redesignated at 51 FR 35216, Oct. 2, 1986]

§ 452.232b Sterile erythromycin lactobionate.

The requirements for certification and the tests and methods of assay for sterile erythromycin lactobionate packaged for dispensing are described in § 452.32a.

[51 FR 35216, Oct. 2, 1986]