

(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]