

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

(8) *Identity test*. Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(3) of that section.

[39 FR 19149, May 30, 1974, as amended at 42 FR 38564, July 29, 1977; 43 FR 9801, Mar. 10, 1978; 50 FR 19920, May 13, 1985]

§ 452.15 Erythromycin estolate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Erythromycin estolate is the lauryl sulfate salt of the propionyl ester of a kind of erythromycin or a mixture of two or more such salts. It occurs as a white powder. It is soluble in alcohol, methyl alcohol, acetone, and chloroform, but is practically insoluble in water. It is so purified and dried that:

(i) It contains not less than 600 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) Its free erythromycin content is not more than 3.0 percent.

(iii) Its moisture content is not more than 4.0 percent.

(iv) Its pH is not less than 4.5 nor more than 7.0.

(v) It gives positive identity tests for erythromycin estolate.

(vi) It is crystalline.

(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 the batch for potency, free erythromycin content, moisture, pH, crystallinity, and identity.

(ii) Samples of the batch: A minimum of 10 containers, each containing not less than 300 milligrams.

(b) *Tests and methods of assay—(1) Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient methyl alcohol to give a concentration of 1.0 milligram of erythromycin base per milliliter (estimated). Immediately dilute this solution further with 0.1M potassium phosphate buffer, pH 8.0 (so-

lution 3), to give a concentration of 0.1 milligram of erythromycin per milliliter (estimated). Hydrolyze 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) *Free erythromycin content*. Proceed as directed in § 436.362 of this chapter.

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

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous suspension containing 10 milligrams per milliliter.

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

(6) *Identity test*. Proceed as directed in § 436.211 of this chapter, preparing the sample as described in paragraph (b)(1) of that section.

[39 FR 19149, May 30, 1974, as amended at 50 FR 19920, May 13, 1985; 53 FR 1920, Jan. 25, 1988]

§ 452.25 Erythromycin ethylsuccinate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Erythromycin ethylsuccinate is the white, odorless, ethylsuccinate ester of erythromycin. It is so purified and dried that:

(i) It contains not less than 765 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) [Reserved]

(iii) Its moisture content is not more than 3.0 percent.

(iv) Its pH is not less than 6.0 and not more than 8.5.

(v) Its residue on ignition is not more than 1.0 percent.

(vi) It gives a positive identity test for erythromycin ethylsuccinate.

(vii) It is crystalline.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 432.5(b) 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 the batch for potency, moisture, pH, residue on ignition, identity, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient methyl alcohol to give a concentration of 1 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) [Reserved]

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

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using a 1.0 percent suspension in water.

(5) *Residue on ignition*. Proceed as directed in § 436.207(a) of this chapter.

(6) *Identity*. Proceed as directed in § 436.211 of this chapter, using the sample prepared as described in paragraph (b)(3) of that section.

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

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

§ 452.25a Sterile erythromycin ethylsuccinate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin ethylsuccinate is the white, odorless, ethylsuccinate ester of erythromycin. It is so purified and dried that:

(i) It contains not less than 765 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) It is sterile.

(iii) [Reserved]

(iv) Its moisture content is not more than 3.0 percent.

(v) Its pH is not less than 6.0 and not more than 8.5.

(vi) Its residue on ignition is not more than 1.0 percent.

(vii) It gives a positive identity test for erythromycin ethylsuccinate.

(viii) It is crystalline.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 432.5(b) 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 the batch for potency, sterility, moisture, pH, residue on ignition, identity, and crystallinity.

(ii) Samples required:

(a) For all tests except sterility: 10 packages, each containing approximately 500 milligrams.

(b) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient methyl alcohol to give a concentration of 1 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)(2) of that section.

(3) [Reserved]

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

(5) *pH*. Proceed as directed in § 436.202 of this chapter, using a 1.0 percent suspension in water.

(6) *Residue on ignition*. Proceed as directed in § 436.207(a) of this chapter.

(7) *Identity*. Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(3) of that section.

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

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

§ 452.30a Sterile erythromycin gluceptate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin gluceptate is the white powder of the glucoheptonic