

(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]

Subpart I [Reserved]

Subpart J—Certain Other Dosage Forms

§ 452.910 Erythromycin for prescription compounding.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin for prescription compounding is the odorless, white to grayish-white or slightly yellow compound of a kind of erythromycin or a mixture of two or more such compounds. It is so purified and dried that:

(i) It contains not less than 850 micrograms of erythromycin per milligram calculated on an anhydrous basis.

(ii) Its moisture content is not more than 10 percent.

(iii) Its pH is not less than 8.0 nor more than 10.5.

(iv) Its residue on ignition is not more than 2.0 percent.

(v) It gives a positive identity test for erythromycin.

(vi) It is crystalline.

(2) *Packaging*. The immediate container shall be a tight container as defined by the United States Pharmacopeia XXI. It shall be so sealed that the contents cannot be used without destroying such seal. Each such container shall contain 10 grams, 25 grams, or 100 grams of erythromycin.

(3) *Labeling*. In addition to the requirements of § 432.5(a)(3) of this chapter, each package shall bear on its outside wrapper or container and on the immediate container the following:

(i) The statement “Caution: Federal law prohibits dispensing without prescription.”

(ii) The statement “Not sterile.”

(iii) The batch mark.

(iv) The number of micrograms of erythromycin activity in each milligram of erythromycin and the number of grams of erythromycin in the immediate container.

(v) The statement “The potency of this drug cannot be assured for longer

than 90 days after the container is first opened for compounding a prescription.”

(vi) The statements “For use only in extemporaneous prescription compounding. Not for manufacturing use.”

(4) *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, moisture, pH, residue on ignition, identity, and crystallinity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing not less than 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 obtain a concentration of 10 milligrams of erythromycin base per milliliter (estimated). Dilute this solution further with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution containing 1.0 milligram of erythromycin base per milliliter (estimated). Further dilute an aliquot of the stock solution 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) *pH*. Proceed as directed in § 436.202 of this chapter, except standardize the pH meter with pH 7.0 and pH 10.0 buffers and prepare the sample as follows: Dissolve 200 milligrams of sample in 5 milliliters of reagent grade methyl alcohol. Add 95 milliliters of water and mix. Record the pH when an equilibrium value has been reached.

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

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

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

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