freshly prepared saturated sodium iodide solution, stopper, and swirl to mix. Let stand in the dark for 30 minutes. Add 50 milliliters of previously boiled and cooled distilled water and titrate the liberated iodine with 0.1*N* sodium thiosulfate, adding starch T.S. near the endpoint. Perform a blank determination and correct the sample titer. Each milliliter of 0.1*N* sodium thiosulfate is equivalent to 12.11 milligrams of benzoyl peroxide. Calculate the benzoyl peroxide content as follows:

$$\text{Percent benzoyl peroxide} = \frac{V_u \times \text{Normality of sodium thiosulfate} \times 12.11}{\text{Sample weight in grams}}$$

where:

V_u=Milliliters of sodium thiosulfate used in the titration of the sample minus the milliliters of sodium thiosulfate used in the titration of the sample blank.

[49 FR 47485, Dec. 5, 1984; 49 FR 49090, Dec. 18, 1984; 49 FR 49449, Dec. 20, 1984, as amended at 55 FR 11584, Mar. 29, 1990]

§ 452.510e Erythromycin topical gel.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin topical gel is erythromycin in a suitable and harmless gel. Each gram contains 20 milligrams of erythromycin. The erythromycin content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1), except with respect to heavy metals.

(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 complying with the requirements of § 431.1 of this chapter, each request shall contain:

(i) Results of tests and assays on:

(A) The erythromycin used in making the batch for potency, moisture, pH, residue on ignition, identity, and crystallinity.

(B) The batch for erythromycin content.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The erythromycin used in making the batch: 5 packages, each containing approximately 100 milligrams.

(B) The batch: A minimum of 8 containers.

(b) *Tests and methods of assay; erythromycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place approximately 1 gram, accurately weighed, of the product into a high-speed glass blender jar containing 200 milliliters of 0.5 percent (volume by volume) polysorbate 80 in 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. 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).

[53 FR 12415, Apr. 14, 1988; 53 FR 16837, May 11, 1988]

Subpart G—[Reserved]

Subpart H—Rectal Dosage Forms

§ 452.710 Erythromycin suppositories.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin suppositories contain in each suppository 125 milligrams of erythromycin in a suitable and harmless base. The erythromycin content is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain. The moisture content is not more than 1.0 percent. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1), (i), (iii), (iv), (v), (vii), and (viii), except its moisture content is not more than 5.0 percent.

(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, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of 30 suppositories.

(b) *Tests 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 suppositories for 3 to 5 minutes in a high-speed glass blender with 200 milliliters of methyl alcohol. Add 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 3 to 5 minutes. Remove an aliquot and 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]

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 0.1*M* 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