

oral suspension is a dry mixture of erythromycin ethylsuccinate and sulfisoxazole acetyl with suitable and harmless flavorings, buffers, surfactants, colorings, and suspending agents. When reconstituted as directed in the labeling, each milliliter will contain erythromycin ethylsuccinate equivalent to 40 milligrams of erythromycin and sulfisoxazole acetyl equivalent to 120 milligrams of sulfisoxazole. Its erythromycin ethylsuccinate content 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. Its sulfisoxazole acetyl content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of sulfisoxazole that it is represented to contain. Its loss on drying is not more than 1.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.0. The erythromycin ethylsuccinate used conforms to the standards prescribed by § 452.25(a)(1). The sulfisoxazole acetyl used conforms to the standards prescribed by the U.S.P.

(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 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 sulfisoxazole acetyl used in making the batch for all U.S.P. specifications.

(c) The batch for erythromycin content, sulfisoxazole content, loss on drying, and pH.

(ii) Samples required:

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

(b) The batch: A minimum of 10 immediate containers.

(b) *Tests and methods of assay—(1) Erythromycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows:

Reconstitute the sample as directed in the labeling. Allow to stand for 1 hour. Shake gently and transfer 5 milliliters of the well-shaken suspension into a high-speed glass blender jar containing 195 milliliters of methyl alcohol. Blend for 3 to 5 minutes. Further dilute an aliquot 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) *Sulfisoxazole acetyl content.* Proceed as directed in § 436.328 of this chapter.

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

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the suspension reconstituted as directed in the labeling.

[46 FR 2990, Jan. 13, 1981, as amended at 50 FR 19921, May 13, 1985]

§ 452.135 Erythromycin stearate oral dosage forms.

§ 452.135a Erythromycin stearate tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Erythromycin stearate tablets are tablets composed of erythromycin stearate with suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains erythromycin stearate equivalent to 75, 100, 125, 250, or 500 milligrams of erythromycin. 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. Tablets shall disintegrate within 1½ hours. The loss on drying is not more than 5.0 percent. The erythromycin stearate used in making the tablets conforms to the standards prescribed by § 452.35(a)(1).

(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 stearate used in making the batch for potency, pH,

moisture, residue on ignition, crystallinity, and identity.

(b) The batch for potency, loss on drying, and disintegration time.

(i) Samples required:

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

(b) The batch: A minimum of 36 tablets.

(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 tablets in a high-speed glass blender with 200 milliliters of methyl alcohol for 3 to 5 minutes. Add 300 milliliters of 0.1M potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 3 to 5 minutes. Further dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

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

(3) *Disintegration time*. Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(2) of that section.

[39 FR 19149, May 30, 1974, as amended at 42 FR 59068, Nov. 15, 1977; 50 FR 19921, May 13, 1985]

§ 452.135b Erythromycin stearate oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin stearate oral suspension is erythromycin stearate with suitable and harmless buffer substances, dispersing agents, diluents, colorings, and flavorings. It contains the equivalent of 25 milligrams of erythromycin per milliliter. 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. Its pH is not less than 7.0 and not more than 8.5. The erythromycin stearate used conforms to the standards prescribed by § 452.35(a)(1).

(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 re-

quirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

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

(b) The batch for potency and pH.

(ii) Samples required:

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

(b) The batch: A minimum of 5 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: Place an accurately measured representative volume of the suspension into a high-speed glass blender jar. Add sufficient methyl alcohol to the jar to give a concentration of 1.25 milligrams of erythromycin base per milliliter (estimated). Blend for 2 to 3 minutes. Add sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a concentration of 0.5 milligrams of erythromycin base per milliliter (estimated) and blend again for 2 to 3 minutes. Further dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *pH*. Proceed as directed in § 436.202 of this chapter, using the undiluted suspension.

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

§ 452.135c Erythromycin stearate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin stearate for oral suspension is a dry mixture of erythromycin stearate with suitable and harmless buffer substances, dispersing agents, diluents, colorings, and flavorings. It contains the equivalent of 25 or 50 milligrams of erythromycin per milliliter of the reconstituted suspension. 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. Its moisture content is not more than 2 percent. When reconstituted as directed in the