

Pipette 5.0 milliliters of the clear, supernatant solution into a 50-milliliter beaker, stir magnetically, and titrate with 0.01*N* perchloric acid, using meth-

yl red as the indicator. The endpoint is the last color change to orange when a drop of titrant is added. Calculate the percent tetracycline base as follows:

$$\text{Percent tetracycline base} = \frac{\text{Milliliters of acid used} \times \text{Normality} \times 0.4445 \times 200}{\text{Weight of sample}}$$

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

[43 FR 11161, Mar. 17, 1978; 43 FR 34456, Aug. 4, 1978, as amended at 50 FR 19920, May 13, 1985]

Subpart B—Oral Dosage Forms

§ 446.110 Chlortetracycline hydrochloride capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Chlortetracycline hydrochloride capsules are composed of chlortetracycline hydrochloride and one or more suitable and harmless diluents, lubricants, and fillers. Each capsule contains 50, 100, or 250 milligrams of chlortetracycline hydrochloride. The potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of chlortetracycline hydrochloride that it is represented to contain. The loss on drying is not more than 1 percent. The chlortetracycline hydrochloride used conforms to the standards prescribed by § 446.10(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 requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The chlortetracycline hydrochloride used in making the batch for potency, loss on drying, pH, crystallinity, and identity.

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

(ii) Samples required:

(a) The chlortetracycline hydrochloride used in making the batch: 10 packages, each containing approximately 300 milligrams.

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

(b) *Test and methods of assay—(1) Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar containing sufficient 0.01*N* hydrochloric acid to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot of the stock solution and further dilute with sterile distilled water to the reference concentration of 0.06 microgram of chlortetracycline hydrochloride per milliliter (estimated).

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

[43 FR 11162, Mar. 17, 1978; 43 FR 34456, Aug. 4, 1978, as amended at 50 FR 19920, May 13, 1985]

§ 446.115 Demeclocycline oral dosage forms.

§ 446.115a Demeclocycline oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Demeclocycline oral suspension is composed of demeclocycline with or without one or more suitable and harmless buffer substances, suspending and stabilizing agents, and preservatives suspended in a suitable and harmless vehicle. Each milliliter contains demeclocycline equivalent to 15 milligrams of demeclocycline hydrochloride. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of demeclocycline hydrochloride equivalent that it is represented to contain. The pH is not less than 4 and not more than 5.8. The demeclocycline used conforms to the standards prescribed by § 446.15(a)(1).