

§ 436.329 of this chapter, except, prepare the working standard and sample solution and calculate the meclocyline content as follows:

(i) *Preparation of standard solution.* Accurately weigh an amount of working standard equivalent to approximately 25 milligrams of meclocyline into a 50-milliliter volumetric flask. Dissolve and dilute to volume with methanol and mix. Transfer exactly 2.0 milliliters of this solution to a 100-milliliter volumetric flask, dilute to volume with mobile phase, and mix.

(ii) *Preparation of sample solution.* Accurately weigh approximately 0.4 to 0.7 gram of sample into a 50-milliliter glass-stoppered centrifuge tube. Add 20 milliliters of methanol and 20 milliliters of 0.025*N* sulfuric acid. Disperse the sample thoroughly by a combination of ultrasonic/vortexing and shak-

ing by hand. Shake for 15 minutes on a wrist action shaker. Quantitatively transfer the contents of the centrifuge tube into a 50-milliliter volumetric flask. Rinse the centrifuge tube with two 5-milliliter portions of methanol and add to the flask. Dilute to volume with methanol and mix. Transfer a portion of the content of the volumetric flask into an appropriate-sized centrifuge tube. Centrifuge for 5 minutes at 2,000 revolutions per minute. Transfer 5.0 milliliters of this solution into a 50-milliliter volumetric flask and dilute to volume with mobile phase and mix. Filter this solution through a 0.5 micrometer filter. Inject the filtrate onto the column as described in § 436.329(e) of this chapter.

(iii) *Calculations.* Calculate the meclocyline content as follows:

$$\text{Meclocyline content of cream in percent} = \frac{A \times 2 \times \text{milligrams of working standard} \times \text{Potency of working standard in micrograms per milligram}}{B \times 100 \times \text{milligrams of sample}}$$

where:

A=Area or peak height of the sample peak (at a retention time equal to that observed for the standard);

B=Area or peak height of the standard peak.

[46 FR 3837, Jan. 16, 1981; 46 FR 21361, Apr. 10, 1981, as amended at 47 FR 22515, May 25, 1982; 50 FR 1504, Jan. 11, 1985]

§ 446.567 Oxytetracycline hydrochloride dermatologic forms. hydrodosage

§ 446.567a [Reserved]

§ 446.567b Oxytetracycline hydrochloride-polymyxin B sulfate topical ointment. hydrodosage

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Oxytetracycline hydrochloride-polymyxin B sulfate topical ointment is oxytetracycline hydrochloride and polymyxin B sulfate in a suitable and harmless ointment base. Each gram contains oxytetracycline hydrochloride equivalent to 30 milligrams of oxytetracycline and polymyxin B sulfate equivalent to 10,000 units of polymyxin B. Its oxytetra-

cycline content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain. Its polymyxin B sulfate content is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of units of polymyxin B that it is represented to contain. Its moisture content is not more than 1 percent. The oxytetracycline hydrochloride used conforms to the standards prescribed by § 446.67(a)(1). The polymyxin B sulfate conforms to the standards prescribed by § 448.30(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5(a)(3) of this chapter, each package shall bear on its label or labeling as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(a) The batch mark.

(b) The name and quantity of each active ingredient contained in the drug.