

the stock solution with distilled water to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using the sample diluted with an equal volume of distilled water.

[44 FR 5881, Jan. 30, 1979, as amended at 48 FR 3961, Jan. 28, 1983; 50 FR 19921, May 13, 1985]

Subpart F—Dermatologic Dosage Forms

§ 455.510 Chloramphenicol dermatologic dosage forms.

§ 455.510a Chloramphenicol ointment (chloramphenicol cream).

The requirements for certification and the tests and methods of assay for chloramphenicol ointment (chloramphenicol cream) are described in § 455.310c.

§ 455.510b [Reserved]

§ 455.510c Chloramphenicol-polymyxin ointment.

The requirements for certification and the tests and methods of assay for chloramphenicol-polymyxin ointment are described in § 455.310d.

§ 455.510d Fibrinolysin and desoxyribonuclease, combined (bovine) with chloramphenicol ointment.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Fibrinolysin and desoxyribonuclease, combined (bovine) with chloramphenicol ointment is fibrinolysin, desoxyribonuclease, and chloramphenicol in a suitable and harmless ointment base. It contains a suitable and harmless preservative. Each gram contains 1 unit of fibrinolysin, 666 units of desoxyribonuclease, and 10 milligrams of chloramphenicol. Its chloramphenicol content is satisfactory if it is not less than 90 percent and not more than 120 per-

cent of the number of milligrams of chloramphenicol that it is represented to contain. The chloramphenicol used conforms to the standards prescribed by § 455.10, except paragraph (b)(2) of that section. In addition to the requirements prescribed by this paragraph, the drug satisfies the requirements designated therefor by the Center for Biologics Evaluation and Research, Food and Drug Administration, Department of Health and Human Services.

(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 chloramphenicol used in making the batch for potency, pH, specific rotation, melting range, absorptivity, and crystallinity.

(b) The batch for potency.

(ii) Samples required:

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

(b) The batch: A minimum of 5 containers if it is packaged in immediate containers of tin or glass, and a minimum of 20 immediate containers if it is packaged in immediate containers other than tin or glass.

(b) *Tests and methods of assay; potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of petroleum ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of distilled water and shake well. Allow the layers to separate. Remove the aqueous layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of distilled water. Combine the aqueous extractives in a suitable volumetric flask and dilute to volume with distilled water. Remove an aliquot and further dilute with distilled water to the reference concentration of 2.5

micrograms of chloramphenicol per milliliter (estimated).

[44 FR 10380, Feb. 20, 1979, as amended at 48 FR 3961, Jan. 28, 1983; 50 FR 19921, May 13, 1985; 55 FR 11585, Mar. 29, 1990]

§ 455.540 Mupirocin ointment.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Mupirocin ointment is mupirocin in a suitable and harmless ointment base. Each gram of ointment contains 20 milligrams of mupirocin. Its mupirocin content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of mupirocin that it is represented to contain. It passes the identity test. The mupirocin used conforms to the standards prescribed by § 455.40(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 mupirocin used in making the batch for potency, moisture, pH, crystallinity, and identity.

(B) The batch for mupirocin content and identity.

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

(A) The mupirocin used in making the batch: 10 packages, each containing not less than 300 milligrams.

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

(b) *Tests and methods of assay—(1) Mupirocin content.* Proceed as directed in § 455.40(b)(1), preparing the sample solution and calculating the mupirocin content as follows:

(i) *Sample solution.* Accurately weigh approximately 0.5 gram of ointment and dissolve in 20 milliliters of acetone-trile. Transfer to a 100-milliliter volumetric flask with the aid of pH 6.3 phosphate buffer. Dilute to volume with pH 6.3 phosphate buffer. Mix well. The sample solution contains approximately 100 micrograms of mupirocin per milliliter (estimated).

(ii) *Calculations.* Calculate the mupirocin content in milligrams per gram as follows:

$$\text{Milligrams of mupirocin per gram} = \frac{A_u \times P_s \times d}{A_s \times 1,000 \times n}$$

where:

A_u =Area of the mupirocin peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s =Area of the mupirocin peak in the chromatogram of the mupirocin working standard;

A_s =Mupirocin activity in the mupirocin working standard solution in micrograms per milliliter;

d =Dilution factor of the sample; and

n =Number of grams of sample assayed.

(2) *Identity.* The high-performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the mupirocin working standard.

[55 FR 2642, Jan. 26, 1990]

PART 460—ANTIBIOTIC DRUGS INTENDED FOR USE IN LABORATORY DIAGNOSIS OF DISEASE

Subpart A—Susceptibility Discs

Sec.

460.1 Certification procedures for antibiotic susceptibility discs.

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Subpart B—Susceptibility Powders

460.25 Bacitracin diagnostic sensitivity powder.

460.28 Disodium carbenicillin diagnostic sensitivity powder.

460.33 Clindamycin hydrochloride hydrate sensitivity powder.

460.38 Sodium colistimethate diagnostic sensitivity powder.

460.42 Dihydrostreptomycin sulfate diagnostic sensitivity powder.

460.47 Doxycycline hyclate diagnostic sensitivity powder.

460.55 Lincomycin hydrochloride monohydrate diagnostic sensitivity powder.

460.58 Methacycline hydrochloride diagnostic sensitivity powder.

460.64 Minocycline hydrochloride powder for