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 acetonitrile. 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.

Subpart B—Susceptibility Powders