

ether. Add 20 milliliters of 0.1 *M* potassium phosphate buffer (pH 8.0) and shake. Remove the buffer layer and repeat the extraction with three additional 20-milliliter portions of the buffer. Place the buffer solution in a second separatory funnel and wash with three 30-milliliter portions of ether. Discard the ether washes. Remove an aliquot of the buffer solution and proceed as directed in § 440.80a(b) (1) of this chapter, except § 440.80a(b)(1)(iv) and (ix) of this chapter. If the iodometric chemical assay is used, proceed as directed in § 440.80a(b)(5)(iv)(a) of this chapter, except prepare the sample as directed in § 536.501(a)(1) of this chapter. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content*. Using an aliquot of the buffer solution prepared as directed in paragraph (a)(1) of this section, proceed as directed in § 444.70a(b)(1) through (9) of this chapter, except add sufficient penicillinase to completely inactivate the penicillin present. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content*. Proceed as directed in paragraph (a)(2) of this section, using the dihydrostreptomycin working standard as the standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(4) *Erythromycin content*. Proceed as directed in § 444.570b(b)(1)(i)(b) of this chapter, except prepare the sample as follows: Place a representative sample (usually approximately 1.0 gram, accurately weighed), in a glass blending jar containing 99 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0, and 1 milliliter of polysorbate 80. Using a high-speed blender, blend for 2 to 3 minutes. Add 100 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0, and blend for an additional 2 to 3 minutes. Prepare an intermediate dilution by diluting an aliquot of the filtrate with 0.1 *M* potassium phosphate buffer (pH 8.0), and add sufficient penicillinase to inactivate the penicillin. Then further di-

lute with buffer to give an erythromycin content of 1.0 microgram per milliliter (estimated). Its content of erythromycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture*. Proceed as directed in § 436.500(c).

[39 FR 18944, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

**§ 436.511 Penicillin-streptomycin-bacitracin methylene disalicylate-neomycin ointment; penicillin-dihydrostreptomycin-bacitracin methylene disalicylate-neomycin ointment.**

(a) *Potency*—(1) *Penicillin content*. Proceed as directed in § 540.380a(b)(1) of this chapter. Its penicillin content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content*. Proceed as directed in § 436.105 of this chapter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content*. Proceed as directed in § 436.105 of this chapter. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(4) *Bacitracin methylene disalicylate content*. Proceed as directed in § 436.505(a)(3). Its potency is satisfactory if it contains not less than 85 percent of the equivalent number of units of bacitracin that it is represented to contain.

(5) *Neomycin content*. Proceed as directed in § 436.105 of this chapter. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture*. Proceed as directed in § 436.201.

[39 FR 18944, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

**§ 436.512 Procaine penicillin G-novobiocin-neomycin-dihydrostreptomycin in oil.**

(a) *Potency*—(1) *Penicillin G content*. Proceed as directed in § 440.180d(b)(1)(i)(a) of this chapter, using the