

polymyxin B, and 10 milligrams of hydrocortisone in a suitable and harmless vehicle. It may also contain one or more suitable and harmless buffers, dispersants, and solvents. Its neomycin sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin 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 130 percent of the number of units of polymyxin B that it is represented to contain. It is sterile. The pH is not less than 2.0 and not more than 4.5. The neomycin sulfate used conforms to the standards prescribed by § 444.42(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1) of this chapter.

(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 the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identity.

(b) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(c) The batch for neomycin content, polymyxin B content, sterility, and pH.

(ii) Samples required:

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

(b) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(c) The batch:

(1) For all tests except sterility: A minimum of six immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with sufficient 0.1M potassium phosphate

buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(ii) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, except add to each concentration of polymyxin B standard response line a quantity of neomycin equal to the amount present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Prepare the sample for assay as follows: Dilute an accurately measured representative portion of the sample with sufficient 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 10 units of polymyxin B 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) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

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## Subpart F—Dermatologic Dosage Forms

### § 444.520 Gentamicin sulfate dermatologic dosage forms.

#### § 444.520a Gentamicin sulfate ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Gentamicin sulfate ointment is gentamicin sulfate with suitable preservatives in a white petrolatum base. Each gram contains gentamicin sulfate equivalent to 1.0 milligram of gentamicin. Its potency is satisfactory if it is not less than 90 percent and not more than 135 percent of the number of milligrams of gentamicin that it is represented to contain. Its moisture content is not more than 1.0 percent. The gentamicin sulfate used conforms to the standards prescribed therefor by § 444.20(a)(1).

(2) *Packaging.* In addition to the requirements of § 432.1 of this chapter, it may be dispensed from a pressurized container wherein it is maintained in a compartment separate from the gas used to supply the pressure.