

of 0.1 microgram of gentamicin per milliliter (estimated).

[39 FR 19046, May 30, 1974, as amended at 46 FR 45332, Sept. 11, 1981; 50 FR 19919, May 13, 1985]

**§ 444.540 Neomycin palmitate dermatologic dosage forms.**

**§ 444.542 Neomycin sulfate dermatologic dosage forms.**

**§ 444.542a Neomycin sulfate ointment; neomycin sulfate- \_\_\_\_\_ ointment (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section).**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate ointment contains, in each gram, 3.5 milligrams of neomycin in a suitable and harmless water-soluble or oleaginous ointment base, with or without one or more suitable and harmless dispersants, emollients, and preservatives. The following other drugs may be combined with neomycin sulfate ointment in the indicated amounts, per gram:

- (i) If it is for topical use:
  - (a) 0.5 milligram of flurandrenolide; or
  - (b) 0.25 milligram of fluorometholone; or
  - (c) 5.0, 10.0, 15.0, or 25.0 milligrams of hydrocortisone acetate; or
  - (d) 10.0 or 25.0 milligrams of hydrocortisone; or
  - (e) 5.0 milligrams of hydrocortamate hydrochloride; or
  - (f) 1.0, 2.5, or 5.0 milligrams of prednisolone acetate; or
  - (g) 1.0 milligram of triamcinolone acetonide; or
  - (h)-(j) [Reserved]
  - (j) 200 milligrams of benzocaine.
- (ii) If it is for ophthalmic use:
  - (a) 5.0 milligrams or 15.0 milligrams of hydrocortisone acetate; or
  - (b) 2.5 milligrams of sodium prednisolone phosphate; or
  - (c) 0.5 milligram of sodium dexamethasone phosphate.
  - (d) 1.0 milligram of methylprednisolone; or
  - (e) 1.0 milligram of triamcinolone acetonide; or

(f) 2.5 milligrams or 5.0 milligrams of prednisolone acetate; or

(g) 15.0 milligrams of cortisone acetate.

If it is an oleaginous base, its moisture content is not more than 1.0 percent. If it is intended for ophthalmic use, it is sterile. The neomycin sulfate used conforms to the standards prescribed by § 444.42a(a)(1)(i), (vi), and (vii). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* If it contains a steroid or if it is intended for ophthalmic use, it shall be labeled in accordance with the requirements prescribed by § 432.5 of this chapter, and its expiration date is 12 months. If it does not contain a steroid or it is not intended for ophthalmic use 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.
- (c) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safely and efficaciously.

(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, pH, and identity.
  - (b) The batch for potency and for moisture if the ointment base is oleaginous and for sterility if the ointment is intended for ophthalmic use.
- (ii) Samples required:
  - (a) The neomycin sulfate used in making the batch: 10 packages each containing approximately 300 milligrams.
  - (b) The batch: