

(b) The gramicidin used in making the batch for potency, moisture, residue on ignition, melting point, crystallinity, and identity.

(c) The batch for neomycin content, gramicidin content, and moisture, and for sterility if it 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 gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(c) The batch:

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

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

(d) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content*. Proceed as directed in §444.542a(b)(1). Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Gramicidin content*. Proceed as directed in §448.25(b)(1) of this chapter, except prepare the sample for assay by the following method: Place an accurately weighed representative portion into a separatory funnel. Dissolve the ointment in approximately 50 milliliters of petroleum ether. Extract this solution with four 20-milliliter portions of 80 percent alcohol prepared from alcohol U.S.P. XX. Combine the extractives in a suitable volumetric flask, bring to volume with alcohol U.S.P. XX, and mix well. From this stock solution, dilute an aliquot with alcohol U.S.P. XX to the reference concentration. Its content of gramicidin is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *Sterility*. If the ointment is intended for ophthalmic use, proceed as

directed in §436.20 of this chapter, using the method described in paragraph (e)(3) of that section. However, if the ointment is not soluble in isopropyl myristate proceed as directed in §436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use 100 milligrams in lieu of 300 milligrams of solids.

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

[39 FR 19046, May 30, 1974, as amended at 47 FR 23709, June 1, 1982; 50 FR 19919, May 13, 1985]

**§ 444.542g Neomycin sulfate-gramicidin-triamcinolone acetamide cream.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Neomycin sulfate-gramicidin-triamcinolone acetamide cream is a cream containing 2.5 milligrams of neomycin, 0.25 milligram of gramicidin, and 1.0 milligram of triamcinolone acetamide per gram, with one or more suitable and harmless emollients, dispersants, and preservatives in a suitable and harmless cream base. The neomycin sulfate used conforms to the standards prescribed by §444.42a(a)(1) (i), (vi), and (vii). The gramicidin used conforms to the standards prescribed by §448.25(a)(1) (i), (iv), (v), and (vi) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., shall conform to the standards prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with the requirements prescribed by §432.5 of this chapter. Its expiration date is 12 months.

(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 gramicidin used in making the batch for potency, residue on ignition, melting point, crystallinity and identity.

(c) The batch for neomycin content and gramicidin content.

(ii) Samples required:

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

(b) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(c) The batch: A minimum of six immediate containers.

(d) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(b) *Tests and methods of assay; potency*—(1) *Neomycin content*. Proceed as directed in §444.542(b). Its neomycin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin that it is represented to contain.

(2) *Gramicidin content*. Proceed as directed in §448.25(b)(1) of this chapter, except to prepare the sample for assay proceed as follows: Place an accurately weighed representative portion into a high-speed glass blender jar and add sufficient alcohol U.S.P. XX to obtain a stock solution of convenient concentration. Blend 3 to 5 minutes. Make proper estimated dilutions of an aliquot to the reference concentration with alcohol U.S.P. XX. Its content of gramicidin is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of gramicidin that it is represented to contain.

[39 FR 19045, May 30, 1974, as amended at 41 FR 10886, Mar. 15, 1976; 47 FR 23709, June 1, 1982]

**§444.542h Neomycin sulfate-gramicidin-triamcinolone acetonide lotion; neomycin sulfate-gramicidin-fludrocortisone acetate lotion.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity*. The drug is a lotion containing, in each milliliter, 2.5 milligrams of neomycin, 0.25 milligram of gramicidin, and either 1 milligram of triamcinolone acetonide or 1 milligram of fludrocortisone acetate, with one or more suitable and harmless emollients, buffers, dispersants, and preservatives, in a suitable and harmless lotion base. The neomycin sulfate used conforms to

the standards prescribed by §444.42a(a)(1)(i), (vi), and (vii). The gramicidin used conforms to the standards prescribed by §448.25(a)(1)(i), (iv), (v), and (vi) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the requirements prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with the requirements of §432.5 of this chapter. Its expiration date is 12 months.

(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 gramicidin used in making the batch for potency, crystallinity, residue on ignition, melting point, and identity.

(c) The batch for neomycin content and gramicidin content.

(ii) Samples required:

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

(b) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(c) The batch: A minimum of 6 immediate containers.

(d) In case of an initial request for certification, each other substance used in making the batch: One package of each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content*. Proceed as directed in §444.542c(b). Its neomycin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Gramicidin content*. Proceed as directed in §448.25(b)(1) of this chapter, except prepare the sample by placing an accurately measured representative portion into a high-speed glass blender jar with sufficient alcohol U.S.P. XX to obtain a stock solution of convenience concentration. Blend 3 to 5 minutes.