

## Subparts G–I [Reserved]

## Subpart J—Certain Other Dosage Forms

**§ 444.942 Neomycin sulfate in certain other dosage forms.****§ 444.942a Neomycin sulfate for compounding oral products.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Neomycin sulfate for compounding oral products is the sulfate salt of a kind of neomycin or a mixture of two or more such salts. It is so purified and dried that:

(i) It has a potency of not less than 600 micrograms of neomycin per milligram.

(ii) [Reserved]

(iii) Its moisture content is not more than 8 percent.

(iv) Its pH is an aqueous solution containing 33 milligrams per milliliter is not less than 5.0 nor more than 7.5.

(v) It gives a positive identity test for neomycin.

(2) *Packaging.* The immediate container shall be of colorless, transparent glass and it shall be a tight container as defined by the U.S.P. It shall be so sealed that the contents cannot be used without destroying such seal. Each such container shall contain not less than 10 grams and not more than 100 grams of neomycin sulfate.

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

(4) *Requests for certification; samples.*

(i) In addition to complying with the conditions of § 431.1 of this chapter, a person who requests certification of a batch of neomycin sulfate for compounding oral products shall submit with the request a statement showing the batch mark, the number of packages of each size in the batch, and the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by results of tests and assays made on the batch for potency, moisture, pH, and identity.

(ii) Such person shall submit with his request a sample consisting of a 0.5 gram portion for each 5,000 packages in

the batch, but in no case less than 10 such portions. Each such portion shall be collected at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay; potency, moisture, pH, and identity.* Proceed as directed in § 444.42a(b) (1), (5), (6), and (7).

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985; 53 FR 12658, Apr. 15, 1988; 53 FR 31837, Aug. 22, 1988]

**§ 444.942b Sterile neomycin sulfate and polymyxin B sulfate solution.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Sterile neomycin sulfate and polymyxin B sulfate solution is an aqueous solution containing in each milliliter 40 milligrams of neomycin and 200,000 units of polymyxin B. If packaged in a multiple-dose container, it shall contain a suitable and harmless preservative. It is sterile. Its pH is not less than 4.5 and not more than 6.0, except that for issuance of a certificate it is not less than 5.0. The neomycin sulfate used conforms to the standards prescribed by § 444.42a(a)(1) (i), (vi), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30a(a)(1) (i), (vi), (vii), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or the N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* In addition to being labeled in accordance with the requirements of § 432.5 of this chapter, the labeling shall include a statement to the effect that the drug is to be diluted for use as a urinary bladder irrigant and is not for injection. 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 polymyxin B sulfate used in making the batch for potency, pH, residue on ignition, and identity.