

## 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.

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

(ii) Samples required:

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

(b) The polymyxin B sulfate used in making the batch: Ten 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: Twenty 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 §444.42a(b)(1), except prepare the sample as follows: Remove an accurately measured portion and dilute with 0.1M potassium phosphate buffer, pH 8.0, to the proper prescribed reference concentration. The neomycin content is satisfactory if it is not less than 90 percent nor more than 130 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Polymyxin B content*. Remove an accurately measured portion and dilute with 10-percent potassium phosphate buffer, pH 6.0, to a reference concentration of 10 units of polymyxin B per milliliter. Proceed as directed in §448.30a(b)(1) of this chapter, except add to each concentration of the polymyxin B standard curve a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. The polymyxin B content is satisfactory if it is not less than 90 percent nor more than 130 percent of the number of units of polymyxin B that it is represented to contain.

(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 §440.80a(b)(5)(ii) of this chapter, using the undiluted sample.

[39 FR 19045, May 30, 1974, as amended at 41 FR 56307, Dec. 28, 1976; 42 FR 18059, Apr. 5, 1977; 50 FR 19919, May 13, 1985]

## PART 446—TETRACYCLINE ANTIBIOTIC DRUGS

### Subpart A—Bulk Drugs

Sec.

- 446.10 Chlortetracycline hydrochloride.
- 446.10a Sterile chlortetracycline hydrochloride.
- 446.15 Demeclocycline.
- 446.16 Demeclocycline hydrochloride.
- 446.20 Doxycycline hyclate.
- 446.20a Sterile doxycycline hyclate.
- 446.21 Doxycycline monohydrate.
- 446.42 Meclocyline sulfosalicylate.
- 446.50 Methacycline hydrochloride.
- 446.60 Minocycline hydrochloride.
- 446.65 Oxytetracycline.
- 446.65a Sterile oxytetracycline.
- 446.66 Oxytetracycline calcium.
- 446.67 Oxytetracycline hydrochloride.
- 446.67a Sterile oxytetracycline hydrochloride.
- 446.75a Sterile rolitetracycline.
- 446.76a Sterile rolitetracycline nitrate.
- 446.80 Tetracycline.
- 446.81 Tetracycline hydrochloride.
- 446.81a Sterile tetracycline hydrochloride.
- 446.82 Tetracycline phosphate complex.

### Subpart B—Oral Dosage Forms

- 446.110 Chlortetracycline hydrochloride capsules.
- 446.115 Demeclocycline oral dosage forms.
- 446.115a Demeclocycline oral suspension.
- 446.115b Demeclocycline for oral suspension.
- 446.116 Demeclocycline hydrochloride oral dosage forms.
- 446.116a Demeclocycline hydrochloride tablets.
- 446.116b [Reserved]
- 446.116c Demeclocycline hydrochloride capsules.
- 446.120 Doxycycline hyclate oral dosage forms.
- 446.120a Doxycycline hyclate capsules.
- 446.120b Doxycycline calcium oral suspension.
- 446.120c Doxycycline hyclate tablets.
- 446.120d Doxycycline hyclate pellet-filled capsules.
- 446.121 Doxycycline monohydrate oral dosage forms.
- 446.121a Doxycycline monohydrate for oral suspension.
- 446.121b Doxycycline monohydrate capsules.
- 446.150 Methacycline hydrochloride oral dosage forms.
- 446.150a Methacycline hydrochloride capsules.
- 446.150b Methacycline hydrochloride oral suspension.
- 446.160 Minocycline hydrochloride oral dosage forms.
- 446.160a Minocycline hydrochloride tablets.