

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

(b) The batch for potency and pH.

(ii) Samples required:

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

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

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, except prepare the sample as follows: Remove an accurately measured representative portion with a suitable syringe, and dilute with sufficient 0.1 M potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Further dilute with solution 3 to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(2) *pH*. Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 444.150 Paromomycin sulfate oral dosage forms.

§ 444.150a Paromomycin sulfate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Paromomycin sulfate capsules are paromomycin sulfate enclosed in a suitable and harmless gelatin capsule. Each capsule contains 250 milligrams of paromomycin. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of paromomycin that it is represented to contain. The loss on drying is not more than 7.0 percent. The paromomycin sulfate used conforms to the standards prescribed therefor by § 444.50(a)(1).

(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 paromomycin sulfate used in making the batch for potency, loss on

drying, pH, specific rotation, and residue on ignition.

(b) The batch for potency and loss on drying.

(ii) Samples required:

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

(b) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend a representative number of capsules for 3 to 5 minutes in a high-speed glass blender with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Further dilute the stock solution with solution 3 to the reference concentration of 1.0 microgram of paromomycin per milliliter (estimated).

(2) *Loss on drying*. Proceed as directed in § 436.200(b) of this chapter.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 444.150b Paromomycin sulfate sirup.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Paromomycin sulfate sirup contains the equivalent of 25 milligrams of paromomycin per milliliter. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of paromomycin that it is represented to contain. It may contain one or more suitable and harmless solvents, flavorings, colorings, preservatives, and buffers in water. Its pH is not less than 7.5 and not more than 8.5. The paromomycin sulfate used conforms to the requirements of § 444.50(a)(1) (i), (ii), (iv), (v), and (vi).

(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 for:

(a) The paromomycin sulfate used in making the batch for potency, pH, specific rotation, and residue on ignition.

(b) The batch for potency and pH.

(ii) Samples required:

(a) The paromomycin sulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(b) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Remove an appropriate aliquot of the sirup and transfer to an appropriate-sized volumetric flask. Dilute to volume with 0.1M potassium phosphate buffer, pH 8.0 (solution 3), and mix well. Further dilute with solution 3 to the reference concentration of 1.0 microgram of paromomycin per milliliter (estimated).

(2) *pH*. Proceed as directed in §436.202 of this chapter, using the undiluted sample.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

Subpart C—Injectable Dosage Forms

§ 444.206 Amikacin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Amikacin sulfate injection is an aqueous solution of amikacin with suitable and harmless buffer substances and preservatives. Each milliliter contains amikacin sulfate equivalent to either 50 milligrams or 250 milligrams of amikacin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of amikacin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 3.5 and not more than 5.5. The amikacin used conforms to the standards prescribed by §444.6(a)(1) or, if amikacin sulfate is used, to the standards prescribed by §444.7(a)(1).

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

(i) Results of tests and assays on:

(a) The amikacin used in making the batch for potency, moisture, pH, identity, residue on ignition, specific rotation, and crystallinity.

(b) The batch for potency, sterility, pyrogens, and pH.

(i) Samples required:

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

(b) The batch:

(1) For all tests except sterility: A minimum of 12 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*. Proceed as directed in §436.106 of this chapter, preparing the sample for assay as follows: Place an accurately measured representative portion of the sample into an appropriate-sized volumetric flask and dilute to volume with sterile distilled water to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with sterile distilled water to the reference concentration of 10.0 micrograms of amikacin 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) *Pyrogens*. Proceed as directed in §436.32(b) of this chapter, using a solution containing 25 milligrams of amikacin per milliliter.

(4) [Reserved]

(5) *pH*. Proceed as directed in §436.202 of this chapter, using the undiluted solution.

[41 FR 49483, Nov. 9, 1976, as amended at 50 FR 19919, May 13, 1985; 55 FR 38677, Sept. 20, 1990]

§ 444.220 Gentamicin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Gentamicin sulfate injection is an aqueous solution of gentamicin sulfate with or without one or more suitable buffers, sequestering agents, tonicity agents, or preservatives. Each milliliter contains gentamicin sulfate equivalent to either 0.4, 0.6, 0.7, 0.8, 0.9, 1.0, 1.2, 1.6, 2.0, 2.4, 10.0, or 40 milligrams of gentamicin. Its potency is satisfactory if it contains