

dilute with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(3) of that section.

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

(4) *Metal particles*. Proceed as directed in § 436.206 of this chapter.

[42 FR 27231, May 27, 1977, as amended at 47 FR 23443, May 28, 1982; 48 FR 21564, May 13, 1983; 50 FR 19920, May 13, 1985]

§ 448.321 Colistin sulfate for ophthalmic solution.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Colistin sulfate for ophthalmic solution is a dry mixture of colistin sulfate and mannitol packaged in combination with a suitable and harmless diluting solution which contains buffers and a preservative. When reconstituted as directed in the labeling, each milliliter contains 1.2 milligrams of colistin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of colistin that it is represented to contain. It is sterile. Its loss on drying is not more than 5 percent. When reconstituted as directed in the labeling, its pH is not less than 5.5 and not more than 6.3. The colistin sulfate used conforms to the standards prescribed by § 448.21(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 colistin sulfate used in making the batch for potency, loss on drying, pH, and identity.

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

(ii) Samples required:

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

(b) The batch:

(1) For all tests except sterility: A minimum of 6 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 § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Remove an accurately measured representative portion of the reconstituted solution and dilute with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 1.0 microgram of colistin 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) *Loss on drying*. Proceed as directed in § 436.200(b) of this chapter.

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using the solution reconstituted as directed in the labeling.

[39 FR 19115, May 30, 1974, as amended at 50 FR 19920, May 13, 1985]

§ 448.330 Polymyxin B sulfate-trimethoprim hemisulfate ophthalmic solution.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Polymyxin B sulfate-trimethoprim hemisulfate ophthalmic solution contains, in each milliliter, 10,000 units of polymyxin B and 1.0 milligram of trimethoprim in a suitable and harmless isotonic aqueous vehicle. It contains suitable and harmless buffers and preservatives. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. Its trimethoprim content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of trimethoprim that it is represented to contain. It is sterile. Its pH is not less than 3.0 and not more than 5.5. The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(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: