

and purity. Bacitracin zinc ointment is composed of 500 units of bacitracin zinc per gram in a suitable ointment base. Its potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of bacitracin that it is represented to contain. Its moisture content is not more than 0.5 percent. The bacitracin zinc used conforms to the standards prescribed by § 448.13(a)(1).

(2) *Labeling*—(i) On the label of the immediate container and on the outside wrapper or container, if any:

(a) The batch mark.

(b) The name and quantity of each active ingredient contained in the drug.

(c) An expiration date that conforms to the requirements prescribed by § 432.5(a)(3) of this chapter.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safely and efficaciously.

(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 bacitracin zinc used in making the batch for potency, loss on drying, pH, zinc content, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The bacitracin zinc used in making the batch: 10 packages, each containing 1.0 gram.

(b) The batch: A minimum of six 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: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 0.01*N* hydrochloric acid and shake well. Allow the layers to separate. Remove the acid layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of 0.01*N* hydrochloric acid. Combine the acid extractives in a suitable volumetric flask and dilute to vol-

ume with 0.01*N* hydrochloric acid. (If the bacitracin content is less than 100 units per milliliter in 0.01*N* hydrochloric acid, add sufficient additional hydrochloric acid to each concentration of the standard response line so that each standard solution contains the same amount of acid as the 1.0 unit per milliliter sample solution.) Remove an aliquot and further dilute with 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

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

[42 FR 27237, May 27, 1977, as amended at 50 FR 19920, May 13, 1985]

Subpart G—Vaginal Dosage Forms [Reserved]

Subparts H–I [Reserved]

Subpart J—Certain Other Dosage Forms

§ 448.910 Bacitracin for prescription compounding.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin for prescription compounding is a white to brown, neutral, water-soluble polypeptide intended for use in the extemporaneous compounding of prescriptions by practicing pharmacists. It is so purified and dried that:

(i) Its potency is not less than 40 units of bacitracin per milligram.

(ii) [Reserved]

(iii) Its loss on drying is not more than 5.0 percent.

(iv) Its pH in an aqueous solution containing 10,000 units per milliliter is not less than 5.5 and not more than 7.5.

(v) It passes the identity test.

(2) *Packaging.* The immediate container shall be of colorless, transparent glass, and it shall be a tight container as defined by the United States Pharmacopeia (U.S.P.). It shall be so sealed that the contents cannot be used without destroying such seal. Each such container shall contain 500,000 or 5 million units of bacitracin.

(3) *Labeling.* Each package shall bear on its outside wrapper or container and

on the immediate container the following:

(i) The statement “Caution: Federal law prohibits dispensing without prescription”.

(ii) The statement “Not sterile”.

(iii) The batch mark.

(iv) The number of units of bacitracin activity in each milligram and the number of grams of bacitracin in the immediate container.

(v) The statement “Expiration date _____”, the blank being filled in with the date that is 12 months after the month during which the batch was certified, unless the use of a longer dating period has been approved in accordance with §432.5(a)(3) of this chapter.

(vi) The statement “The potency of this drug cannot be assured for longer than 60 days after the container is first opened for compounding a prescription”.

(vii) The statements, “For use only in extemporaneous prescription compounding. Not for manufacturing use”.

(4) *Requests for certification; samples.* In addition to the requirements of §432.1 of this chapter, each request shall contain:

(i) Results of tests and assays on the batch for potency, loss on drying, pH, and identity.

(ii) Samples required: 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—(1) Potency.* Proceed as directed for bacitracin zinc in §436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution of convenient concentration. Remove an aliquot of the stock solution, add sufficient hydrochloric acid so that the amount of acid in the final solution will be the same as in the reference concentration of the working standard and further dilute with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

(2) [Reserved]

(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 an aqueous solution containing 10,000 units per milliliter.

(5) *Identity.* Proceed as directed in §436.319 of this chapter.

[42 FR 27238, May 27, 1977, as amended at 50 FR 19920, May 13, 1985]

§448.913 Bacitracin zinc for prescription compounding.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Bacitracin zinc for prescription compounding is the zinc salt of a kind of bacitracin or a mixture of two or more such salts intended for use in the extemporaneous compounding of prescriptions by practicing pharmacists. It is so purified and dried that:

(i) Its potency is not less than 40 units of bacitracin per milligram.

(ii) [Reserved]

(iii) Its loss on drying is not more than 5.0 percent.

(iv) Its pH in a saturated aqueous solution is not less than 6.0 and not more than 7.5.

(v) Its zinc content is not more than 10 percent by weight on a moisture-free basis.

(vi) It passes the identity test.

(2) *Packaging.* The immediate container shall be of colorless, transparent glass and it shall be a tight container as defined by the United States Pharmacopeia (U.S.P.). It shall be so sealed that the contents cannot be used without destroying such seal. Each such container shall contain 500,000 or 5 million units of bacitracin.

(3) *Labeling.* Each package shall bear on its outside wrapper or container and on the immediate container the following:

(i) The statement “Caution: Federal law prohibits dispensing without prescription”.

(ii) The statement “Not sterile”.

(iii) The batch mark.

(iv) The number of units of bacitracin activity in each milligram of the bacitracin zinc, and the number of grams of bacitracin zinc in the immediate container.