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for determining in vitro the sensitivity of microorganisms to carbenicillin. Each vial contains disodium carbenicillin equivalent to not more than 1.0 gram of carbenicillin. The potency of each immediate container is satisfactory if it contains not less than 90 percent and not more than 120 percent of its labeled content. It is sterile. Its moisture content is not more than 6 percent. When reconstituted as directed in the labeling, its pH is not less than 6.0 and not more than 8.0. The disodium carbenicillin used conforms to the standards prescribed by § 440.13a(a)(1) (i), (v), (vi), and (vii) of this chapter.

(2) *Packaging.* It shall conform to the packaging requirements of § 432.1 of this chapter.

(3) *Labeling.* In addition to the requirements of § 432.5(a)(3) of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On its outside wrapper or container and on the immediate container:

(*a*) The statement ''For laboratory diagnostic use only.''

(*b*) The statement ''Sterile.''

(*c*) The batch mark.

(*d*) The number of milligrams of carbenicillin in each immediate container.

(ii) On the circular or other labeling within or attached to the package, adequate information for use of the drug in the clinical laboratory.

(4) *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 disodium carbenicillin used in making the batch for potency, moisture, pH, and identity.

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

(ii) Samples required:

(*a*) The disodium carbenicillin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 20 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. Dilute an aliquot with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 20 micrograms of carbenicillin 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) *Moisture.* Proceed as directed in § 436.201 of this chapter.

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

## § 460.33 Clindamycin hydrochloride hydrate sensitivity powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin hydrochloride hydrate diagnostic sensitivity powder is clindamycin hydrochloride hydrate packaged in vials and intended for use in clinical laboratories for determining in vitro the sensitivity of microorganisms to clindamycin. Each vial contains clindamycin hydrochloride hydrate equivalent to 20 milligrams of clindamycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the amount of clindamycin it is represented to contain. It is sterile. Its moisture content is not more than 6.0 percent. Its pH in a solution containing 20 milligrams of clindamycin per milliliter is not less than 3.0 and not more than 6.5. The clindamycin hydrochloride hydrate used conforms to the standards prescribed by § 453.20(a)(1) (i), (ii), (iv), (v), (vi), and (vii) of this chapter.

(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. It shall be of appropriate size to permit the addition of 20 milliliters of sterile diluent when preparing a stock solution for use in making further dilutions for microbial susceptibility testing.

(3) *Labeling.* In addition to the requirements of §432.5(a)(3) of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On its outside wrapper or container and on the immediate container:

(*a*) The statement ''For laboratory diagnosis only.''

(*b*) The statement ''Sterile''.

(*c*) The batch mark.

(*d*) The number of milligrams of clindamycin in each immediate container.

(ii) On the circular or other labeling within or attached to the package, adequate information for use of the drug in the clinical laboratory.

(4) *Request 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 clindamycin hydrochloride hydrate used in making the batch for clindamycin content, microbiological activity, moisture, pH, crystallinity, and identity.

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

(ii) Samples required:

(*a*) The clindamycin hydrochloride hydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 20 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. Dilute an aliquot of this solution with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of clindamycin 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) *Moisture.* Proceed as directed in §436.201 of this chapter.

(4) *pH.* Proceed as directed in §436.202 of this chapter, using the solution obtained when the vial is reconstituted with 1.0 milliliter of distilled water.

## §460.38 Sodium colistimethate diagnostic sensitivity powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sodium colistimethate diagnostic sensitivity powder is sodium colistimethate packaged in vials and intended for use in clinical laboratories for determining in vitro the sensitivity of microorganisms to sodium colistimethate. Each vial contains sodium colistimethate equivalent to 100 milligrams of colistin base activity. It is sterile. Its moisture content is not more than 9.0 percent. When reconstituted as directed in the labeling, its pH is not less than 6.5 and not more than 9.0. It gives a positive identity test for sodium colistimethate. The sodium colistimethate used conforms to the standards prescribed by §448.20a(a)(1)(i), (vi), (vii), and (viii) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(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. It shall be of appropriate size to permit the addition of 20 milliliters of sterile diluent when preparing a stock solution for use in making serial dilutions for microbial susceptibility testing.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On its outside wrapper or container and on the immediate container.

(*a*) The statements ''Not for therapeutic use'' and ''For laboratory diagnosis only''.

(*b*) The statement ''Sterile''.

(*c*) The batch mark.

(*d*) The number of milligrams of colistin base activity in each immediate container.

(*e*) The statements ''Stock solutions are stable for 14 days when refrigerated. For periods of storage up to 6 months, they should be frozen''.

(*f*) Its expiration date which is 12 months, except that the date may be