

percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

(7) *Crystallinity*. Proceed as directed in § 436.203 of this chapter.

[39 FR 19040, May 30, 1974, as amended at 50 FR 19919, May 13, 1985; 52 FR 35912, Sept. 24, 1987]

§ 442.28 Cephalexin hydrochloride monohydrate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cephalexin hydrochloride monohydrate is the hydrochloride salt of 7-(*D*-alpha-amino-alpha-phenylacetamido)-3-methyl-3-cephem-4-carboxylic acid monohydrate. It is so purified and dried that:

(i) Its potency is not less than 800 micrograms and not more than 880 micrograms of cephalexin per milligram on an “as is” basis.

(ii) Its moisture content is not less than 3.0 nor more than 6.5 percent.

(iii) The pH of an aqueous solution containing 10 milligrams per milliliter is not less than 1.5 nor more than 3.0.

(iv) It gives a positive identity test.

(v) It is crystalline.

(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 the batch for cephalexin potency, moisture, pH, identity, and crystallinity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay—(1) Cephalexin potency*. Proceed as directed in § 442.40(b)(1)(ii), except that “cephalexin” is substituted at each occurrence of “cephradine”.

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

(3) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 10 milligrams per milliliter.

(4) *Identity*. Proceed as directed in § 436.367 of this chapter.

(5) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

[54 FR 48860, Nov. 28, 1989]

§ 442.29a Sterile cephalirin sodium.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Sterile cephalirin sodium is the sodium salt of 7-[α (4-pyridylthio)-acetamido]-cephalosporanic acid. It is a white to off-white powder. It is so purified and dried that:

(i) Its potency is not less than 855 micrograms and not more than 1,000 micrograms of cephalirin per milligram on an “as is” basis. If it is packaged for dispensing, its content is satisfactory if it contains not less than 90 percent and not more than 115 percent of the number of milligrams of cephalirin that it is represented to contain.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) [Reserved]

(v) Its moisture content is not more than 2.0 percent.

(vi) Its pH in an aqueous solution containing 10 milligrams of cephalirin per milliliter is not less than 6.5 and not more than 8.5.

(vii) Its cephalirin content is not less than 92 percent and not more than 105 percent on an anhydrous basis.

(viii) It gives a positive identity test for sodium cephalirin.

(ix) It is crystalline.

(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 the batch for potency, sterility, pyrogens, moisture, pH, cephalirin content, identity, and crystallinity.

(ii) Samples required:

(a) If the batch is packaged for re-packing or for use in the manufacture of another drug:

(1) For all tests except sterility: 9 packages, each containing approximately 500 milligrams, and 1 package containing approximately 5 grams.

(2) For sterility testing: 20 packages, each containing approximately 300 milligrams.