

reconstituted as directed in the labeling.

[42 FR 59871, Nov. 22, 1977, as amended at 43 FR 9799, Mar. 10, 1978; 45 FR 22922, Apr. 4, 1980; 50 FR 19918, 19919, May 13, 1985]

§ 440.280c Penicillin G potassium injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillin G potassium injection is a frozen, aqueous, iso-osmotic solution of penicillin G potassium which may contain one or more suitable and harmless buffer substances and a tonicity adjusting agent. Each milliliter contains penicillin G potassium equivalent to 20,000, 40,000, or 60,000 units of penicillin G. Its penicillin G content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 5.5 and not more than 8.0. The penicillin G potassium used conforms to the standards prescribed by § 440.80(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter. In addition, this drug shall be labeled "penicillin G potassium injection".

(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 penicillin G potassium used in making the batch for potency, loss on drying, pH, penicillin G content, and crystallinity.

(B) The batch for penicillin G content, sterility, pyrogens, and pH.

(ii) Samples, if required by the Center for Drug Evaluation and Research:

(A) The penicillin G potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(B) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay.* Thaw the sample as directed in the labeling.

The sample solution used for testing must be at room temperature.

(1) *Penicillin G content.* Proceed as directed in § 440.280b(b)(1) of this chapter, except use the thawed solution.

(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(a) of this chapter, except inject a sufficient volume of the undiluted solution to deliver 20,000 units of penicillin G per kilogram.

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

[55 FR 38675, Sept. 20, 1990]

§ 440.281 Pencillin G sodium injectable dosage forms.

§ 440.281a Sterile penicillin G sodium.

The requirements for certification and the tests and methods of assay for sterile penicillin G sodium packaged for dispensing are described in § 440.81a.

[42 FR 59872, Nov. 22, 1977]

§ 440.281b Penicillin G sodium for injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillin G sodium for injection is a dry mixture of penicillin G sodium and the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids. It may contain citric acid in a quantity not more than 0.15 percent of its total solids in place of a corresponding amount of sodium citrate. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. Its loss on drying is not more than 1.5 percent. Its pH is not less than 6.0 and not more than 7.5. The penicillin G sodium, buffered, used conforms to the standards prescribed by § 440.1081a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.