

(1) If the person who requests certification is the manufacturer of the batch: A minimum of 36 tablets. If, after tableting, such person packaged the batch into dispensing-size containers: 20 tablets, collected at equal intervals during each day the tablets are being packaged, except that this sample is not required if the tablets are packaged immediately after they are compressed or if the manufacturer has been exempted by the Commissioner from such requirement.

(2) If the person who requests certification is not the manufacturer of the batch (for the purposes of certification, a batch shall be that number of tablets filled by such person into dispensing-size containers during each day's packaging operations): A minimum of 36 tablets collected by taking single tablets at such intervals throughout each day of packaging the tablets so that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation*. Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures*. Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(b) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying*. Proceed as directed in § 436.200(b) of this chapter.

(3) *Disintegration time*. Proceed as directed in § 436.212 of this chapter.

[42 FR 59865, Nov. 22, 1977; 43 FR 3705, Jan. 27, 1978, as amended at 50 FR 19919, May 13, 1985]

§ 440.180c Penicillin G potassium capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality,*

and purity. Penicillin G potassium capsules are composed of penicillin G potassium and a suitable and harmless diluent. Each capsule contains penicillin G potassium equivalent to 250,000 units or 400,000 units of penicillin G. 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. Its loss on drying is not more than 1.5 percent. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1), except sterility and pyrogens.

(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:

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

(b) The batch:

(1) If the person who requests certification is the manufacturer of the batch: Potency and loss on drying of capsules collected during the time of encapsulating the batch; and, unless the capsules are packaged into dispensing-size containers immediately after they are encapsulated or the manufacturer has submitted to the Commissioner, and it has been accepted, information adequate to prove that such tests are not necessary, loss on drying of capsules collected during each day of packaging the batch.

(2) If the person who requests certification is not the manufacturer of the batch: Potency and loss on drying of capsules collected during each day the capsules are being packaged into dispensing-size containers.

(ii) Samples required:

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

(b) The batch:

(1) If the person who requests certification is the manufacturer of the batch: A minimum of 30 capsules. If after encapsulating, such person packaged the batch into dispensing-size

containers: 20 capsules collected at equal intervals during each day the capsules are being packaged, except that this sample is not required if the capsules are packaged immediately after they are filled or if the manufacturer has been exempted by the Commissioner from such requirement.

(2) If the person who requests certification is not the manufacturer of the batch (for the purposes of certification, a batch shall be that number of capsules filed by such person into dispensing-size containers during each day's packaging operations): A minimum of 30 capsules collected by taking single capsules at such intervals throughout each day of packaging the capsules that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation*. Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures*. Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(b) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying*. Proceed as directed in § 436.200(b) of this chapter.

[42 FR 59866, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

§ 440.180f Penicillin G potassium for oral solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Penicillin G potassium for oral solution contains penicillin G potassium and one or more suitable and harmless buffers, colorings, flavorings, diluents, and preservatives. Each milliliter contains penicillin G potassium

equivalent to 20,000 units, 25,000 units, 40,000 units, 50,000 units, 80,000 units, or 100,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of penicillin G that it is represented to contain. Its moisture content is not more than 1 percent. When reconstituted as directed in the labeling, its pH is not less than 5.5 and not more than 7.5. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1), except sterility and pyrogens.

(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:

(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 potency, moisture, and pH.

(ii) Samples required:

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

(b) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation*. Reconstitute as directed in the labeling. Transfer an accurately measured representative portion into a suitable volumetric flask and dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1).

(ii) *Assay procedures*. Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(b) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.