

reference concentration of 1.0 unit of penicillin V 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 59864, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

**§ 440.173c Penicillin V potassium tablets.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillin V potassium tablets are composed of penicillin V potassium with or without one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units), 250 milligrams (400,000 units), or 500 milligrams (800,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its loss on drying is not more than 1.5 percent. It shall disintegrate within 1 hour. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

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

(b) The batch for potency, loss on drying, and disintegration time.

(ii) Samples required:

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

(b) The batch: A minimum of 36 tablets.

(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 V 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, as amended at 50 FR 19919, May 13, 1985]

**§ 440.173d Penicillin V potassium for oral solution.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillin V potassium for oral solution is composed of penicillin V potassium with or without one or more suitable and harmless suspending agents, colorings, flavorings, buffer substances, and preservatives. When reconstituted as directed in the labeling, each milliliter contains penicillin V potassium equivalent to either 25 milligrams (40,000 units) or 50 milligrams (80,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 135 percent of the number of milligrams or units of penicillin V 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 5.0 and not more than 7.5. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

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

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

(ii) Samples required:

(a) The penicillin V 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. Dilute an accurately measured representative portion of the suspension with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration.

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

(3) *pH.* Proceed as directed in §436.202 of this chapter, using the sample when reconstituted as directed in the labeling.

[42 FR 59865, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

**§ 440.180 Penicillin G potassium oral dosage forms.**

**§ 440.180a Penicillin G potassium tablets.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin potassium tablets are composed of penicillin G potassium

with or without one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains penicillin G potassium equivalent to 100,000 units, 200,000 units, 250,000 units, 400,000 units, 500,000 units, 800,000 units or 1,000,000 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 percent. The tablets shall disintegrate within 1 hour. 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, loss on drying, and disintegration time of tablets collected during the time of tableting the batch; and, unless the tablets are packaged into dispensing-size containers immediately after they are compressed 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 the tablets collected during each day of packaging the batch.

(2) If the person who requests certification is not the manufacturer of the batch: Potency, loss on drying, and disintegration time of tablets collected during each day the tablets 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: