

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 2.0 percent. 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, crystallinity, penicillin V content.

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

(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 30 capsules.

(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.* Using the penicillin V working standard as the standard of comparison, assay by 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.

[42 FR 59864, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

#### § 440.173b Penicillin V potassium chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V potassium chewable tablets are composed of penicillin V potassium with suitable diluents, binders, buffers, colorings, and flavorings. Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams or units of penicillin V that it is represented to contain. The loss on drying is not more than 1.5 percent. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled "penicillin V potassium tablets".

(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 and loss on drying.

(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 30 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.

[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.