

of 2.0 micrograms of nafcillin per milliliter (estimated) for the microbiological agar diffusion assay and to the prescribed concentration for the iodometric assay.

(ii) *Assay procedures.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter.

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

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

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

[39 FR 18976, May 30, 1974, as amended at 42 FR 59862, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

§ 440.149 Oxacillin sodium monohydrate oral dosage forms.

§ 440.149a Oxacillin sodium monohydrate capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Oxacillin sodium monohydrate capsules are composed of oxacillin sodium monohydrate with or without one or more diluents and lubricants, enclosed in a gelatin capsule. Each capsule contains oxacillin sodium monohydrate equivalent to 125, 250, or 500 milligrams of oxacillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of oxacillin that it is represented to contain. Its moisture content is not more than 6.0 percent. The oxacillin sodium monohydrate used conforms to the standards prescribed by § 440.49(a)(1).

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled "oxacillin sodium capsules".

(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 oxacillin sodium monohydrate used in making the batch

for potency, moisture, pH, oxacillin content, crystallinity, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The oxacillin sodium monohydrate 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.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion 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 5 micrograms of oxacillin 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.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59862, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

§ 440.149b Oxacillin sodium monohydrate for oral solution.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Oxacillin sodium monohydrate for oral solution is a mixture of oxacillin sodium monohydrate with one or more suitable colorings, flavorings, buffer substances, stabilizers, and preservatives. When reconstituted as directed in the labeling, each milliliter contains the equivalent of either 25 or 50 milligrams of oxacillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of

oxacillin that it is represented to contain. Its moisture content is not more than 1.0 percent. When reconstituted as directed in its labeling, the pH of the solution is not less than 5.0 and not more than 7.5. The oxacillin sodium monohydrate used conforms to the standards prescribed by § 440.49(a)(1).

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled "oxacillin sodium for oral solution".

(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 oxacillin sodium monohydrate used in making the batch for potency, moisture, pH, oxacillin content, crystallinity, and identity.

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

(ii) Samples required:

(a) The oxacillin sodium monohydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

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

(b) *Tests and methods of assay—(1) Potency—(i) Sample preparation.* Reconstitute as directed in the labeling. Place an accurately measured representative aliquot of the sample into an appropriate-sized volumetric flask with sufficient 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 microbiological agar diffusion 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 5 micrograms of oxacillin 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 drug reconstituted as directed in the labeling.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59862, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

§ 440.155 Penicillin G benzathine oral dosage forms.

§§ 440.155a—440.155b [Reserved]

§ 440.155c Penicillin G benzathine oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillin G benzathine oral suspension contains penicillin G benzathine with one or more suitable dispersing agents, buffer substances, preservatives, colorings, and flavorings. Each milliliter contains penicillin G benzathine equivalent to 30,000 units or 60,000 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 pH is not less than 6.0 and not more than 7.0. The penicillin G benzathine used conforms to the standards prescribed by § 440.55a(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 benzathine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(b) The batch for potency and pH.

(ii) Samples required:

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

(b) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay—(1) Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this