

dilute with distilled water to the prescribed concentration of cephalexin.

NOTE: The 10.0 milliliters of 0.01*N* iodine must be added within 20 seconds after the addition of the 2.0 milliliters of 1.2*N* hydrochloric acid, and the assay should be completed within 1 hour after the sample and standard are first put into solution.

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

(3) *Disintegration time*. Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(1) of that section.

[39 FR 19040, May 30, 1974, as amended at 40 FR 49083, Oct. 21, 1975; 50 FR 19919, May 13, 1985; 52 FR 20710, June 3, 1987]

**§ 442.127b Cephalexin monohydrate capsules.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Cephalexin monohydrate capsules are composed of cephalexin monohydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains cephalexin monohydrate equivalent to either 125, 250, or 500 milligrams of cephalexin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephalexin that it is represented to contain. Its moisture content is not more than 10 percent. The cephalexin monohydrate used conforms to the standards prescribed by § 442.27(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 cephalexin monohydrate used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The cephalexin 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*. Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar with 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. Remove an aliquot and further dilute with solution 1 to the reference concentration of 20.0 micrograms of cephalexin per milliliter (estimated).

(ii) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Blend a representative number of capsules in a high-speed glass blender with sufficient distilled water to give a stock solution of convenient concentration. Further dilute with distilled water to the prescribed concentration of cephalexin.

NOTE: The 10.0 milliliters of 0.01*N* iodine must be added within 20 seconds after the addition of the 2.0 milliliters of 1.2*N* hydrochloric acid, and the assay should be completed within 1 hour after the sample and standard are first put into solution.

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

[39 FR 19040, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

**§ 442.127c Cephalexin monohydrate for oral suspension.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Cephalexin monohydrate for oral suspension is cephalexin monohydrate with one or more suitable and harmless diluents, buffer substances, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains cephalexin monohydrate equivalent to 25 milligrams, 50 milligrams, or 100 milligrams of cephalexin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephalexin that it is represented to contain. Its moisture content is not

more than 2 percent. When reconstituted as directed in the labeling, its pH is not less than 3.0 and not more than 6.0. The cephalixin used conforms to the standards prescribed by § 442.27(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 cephalixin used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

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

(ii) Samples required:

(a) The cephalixin 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.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the sample as directed in the labeling. Transfer an accurately measured representative portion of the suspension into an appropriate-sized volumetric flask and dilute to volume with 1-percent potassium phosphate buffer, pH 6.0 (solution 1). Further dilute an aliquot of this solution with solution 1 to the reference concentration of 20.0 micrograms of cephalixin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Reconstitute the sample as directed in the labeling. Transfer an accurately measured representative portion to a volumetric flask and bring to volume with distilled water. Further dilute an aliquot of this solution with distilled water to the prescribed concentration of cephalixin.

NOTE: The 10 milliliters of 0.01*N* iodine must be added within 20 seconds after the addition of the 2.0 milliliters of 1.2*N* hydro-

chloric acid, and the assay should be completed within 1 hour after the sample and standard are first put into solution.

(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 19040, May 30, 1974, as amended at 45 FR 16472, Mar. 14, 1980; 50 FR 19919, May 13, 1985]

#### § 442.128 Cephalixin hydrochloride monohydrate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephalixin hydrochloride monohydrate tablets are composed of cephalixin hydrochloride monohydrate and one or more suitable and harmless lubricants, colorings and coating substances. Each tablet contains cephalixin hydrochloride monohydrate equivalent to 250 milligrams, 333 milligrams or 500 milligrams of cephalixin. Its cephalixin content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephalixin that it is represented to contain. Its moisture content is not more than 8.0 percent. The tablets pass the dissolution test. It passes the identity test. The cephalixin hydrochloride monohydrate used conforms to the standards prescribed by § 442.28(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 cephalixin hydrochloride monohydrate used in making the batch for cephalixin potency, moisture, pH, identity, and crystallinity.

(B) The batch for cephalixin content, moisture, dissolution, and identity.

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

(A) The cephalixin hydrochloride monohydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.

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