

§ 442.121

21 CFR Ch. I (4–1–98 Edition)

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

(4) *pH*. Reconstitute as directed in the labeling and proceed as directed in § 436.202 of this chapter.

(5) *Identity*. The high-performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the cefuroxime axetil working standard.

[60 FR 27222, May 23, 1995]

§ 442.121 Cephaloglycin dihydrate oral dosage forms.

§ 442.121a Cephaloglycin dihydrate capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Cephaloglycin dihydrate capsules are composed of cephaloglycin dihydrate and one or more suitable lubricants and diluents enclosed in a gelatin capsule. Each capsule contains cephaloglycin dihydrate equivalent to 250 milligrams of cephaloglycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephaloglycin that it is represented to contain. Its moisture content is not more than 9 percent. The cephaloglycin used conforms to the standards prescribed by § 442.21(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 the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The cephaloglycin dihydrate used in making the batch for potency, moisture, pH, cephaloglycin content, identity, and crystallinity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The cephaloglycin dihydrate 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*. 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 0.1M potassium phosphate buffer, pH 4.5 (solution 4), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 4 to the reference concentration of 10 micrograms of cephaloglycin per milliliter (estimated).

(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]

§ 442.121b Cephaloglycin dihydrate for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Cephaloglycin dihydrate for oral suspension is cephaloglycin dihydrate with one or more suitable diluents, buffer substances, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains cephaloglycin dihydrate equivalent to 50 milligrams of cephaloglycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephaloglycin 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 5.0. It passes the identity test for the presence of the cephaloglycin moiety. The cephaloglycin dihydrate used conforms to the standards prescribed by § 442.21(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 cephaloglycin dihydrate used in making the batch for potency, moisture, pH, cephaloglycin content, identity, and crystallinity.

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

(ii) Samples required:

(a) The cephaloglycin dihydrate used in making the batch: 10 packages, each

containing approximately 500 milligrams.

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

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Place an accurately measured representative portion of the suspension into an appropriately sized volumetric flask and dilute to volume with 0.1M potassium phosphate buffer, pH 4.5 (solution 4). Further dilute an aliquot of the stock solution with solution 4 to the reference concentration of 10 micrograms of cephaloglycin per milliliter (estimated).

(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.

(4) *Identity*. Dilute a representative portion of the sample with sufficient distilled water to give a concentration of 2.5 milligrams of cephaloglycin per milliliter (estimated). Shake vigorously on a mechanical shaker for 30 minutes. Filter through Whatman No. 1 filter paper, discarding the first few milliliters of filtrate. Further dilute an aliquot of the filtrate with sufficient distilled water to give a concentration of 0.05 milligram of cephaloglycin per milliliter (estimated). Using a suitable spectrophotometer, record the ultraviolet absorption spectrum of this solution from 230 to 320 nanometers. The spectrum compares qualitatively to that of the cephaloglycin working standard similarly treated.

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

§ 442.127 Cephalexin monohydrate oral dosage forms.

§ 442.127a Cephalexin monohydrate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Cephalexin monohydrate tablets are composed of cephalexin monohydrate and one or more suitable and harmless diluents, binders, lubricants, colorings, and coating substances. Each tablet contains

cephalexin monohydrate equivalent to 250, 500, or 1,000 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 9 percent. The tablets disintegrate within 30 minutes. 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, moisture, and disintegration time.

(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 36 tablets.

(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 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. 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 tablets in a high-speed glass blender with sufficient distilled water to give a stock solution of convenient concentration. Further