

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

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using a carbon dioxide free aqueous solution containing 5 milligrams of cefprozil per milliliter.

(5) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

(6) *Identity*—(i) *Infrared*. Proceed as directed in § 436.211 of this chapter, using a 1.0 percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

(ii) *High performance liquid chromatography (HPLC)*. The HPLC retention times for the responses of the cefprozil isomers in the assay preparation of the sample must be within 2 percent of the HPLC retention times of the responses of the corresponding cefprozil working standards.

[58 FR 26660, May 4, 1993]

Subpart B—Oral Dosage Forms

§ 442.104 Cefaclor monohydrate oral dosage forms.

§ 442.104a Cefaclor monohydrate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Cefaclor monohydrate capsules are composed of cefaclor monohydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains cefaclor monohydrate equivalent to either 250 milligrams or 500 milligrams of cefaclor. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefaclor that it is represented to contain. Its moisture content is not more than 8.0 percent. The cefaclor monohydrate used conforms to the standards prescribed by § 442.4(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 cefaclor monohydrate used in making the batch for potency, moisture, pH, identity, and crystallinity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The cefaclor 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*. Proceed as directed in § 442.40(b)(1)(ii) of this chapter, except prepare the working standard and sample solutions and calculate the potency of the sample as follows:

(i) *Preparation of working standard solution*. Dissolve and dilute an accurately weighed portion of the cefaclor working standard in sufficient 0.1M potassium phosphate buffer, pH 4.5 (as described in § 436.101(a)(4) of this chapter) to obtain a concentration of 1 milligram of cefaclor per milliliter.

(ii) *Preparation of sample solution*. Place one capsule into a high-speed glass blender jar containing sufficient 0.1M potassium phosphate buffer, pH 4.5 (as described in § 436.101(a)(4) of this chapter) to obtain a concentration of 1 milligram of cefaclor per milliliter. Filter a portion to be used through a 10-micron filter.

(iii) *Calculations*. Calculate the cefaclor content in milligrams per capsule as follows:

$$\text{Milligrams of cefaclor per capsule} = \frac{A_u \times P_a \times d}{A_s \times 1,000}$$

where:

A_u = Absorbance of sample solution;

P_a = Potency of working standard in micrograms per milliliter;

A_s = Absorbance of working standard solution;

d = Dilution factor of the sample.

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

[46 FR 3833, Jan. 16, 1981; 46 FR 21360, Apr. 10, 1981]

§ 442.104b Cefaclor monohydrate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Cefaclor monohydrate for oral suspension is cefaclor monohydrate with one or more suitable

and harmless diluents, buffer substances, colorings and flavorings. When reconstituted as directed in the labeling, each milliliter contains cefaclor monohydrate equivalent to 25 milligrams, 37.5 milligrams, 50 milligrams, or 75 milligrams of cefaclor. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefaclor that it is represented to contain. Its moisture content is not more than 2.0 percent. When reconstituted as directed in the labeling, its pH is not less than 2.5 and not more than 5.0. The cefaclor monohydrate used conforms to the standards prescribed by § 442.4(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 cefaclor monohydrate used in making the batch for potency, moisture, pH, identity, and crystallinity.

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

(ii) Samples required:

(a) The cefaclor 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.* Proceed as directed in § 442.40(b)(1)(ii) of this chapter, except prepare the working standard and sample solutions and calculate the potency of the sample as follows:

(i) *Preparation of working standard solution.* Dissolve and dilute an accurately weighed portion of the cefaclor working standard in sufficient 0.1M potassium phosphate buffer, pH 4.5 (as described in § 436.101(a)(4) of this chapter) to obtain a concentration of 1 milligram of cefaclor per milliliter.

(ii) *Preparation of sample solution.* Reconstitute the sample as directed in the labeling. Transfer a 5.0-milliliter portion into an appropriate-sized volumetric flask and dilute to volume with 0.1M potassium phosphate buffer, pH 4.5 (as described in § 436.101(a)(4) of this

chapter) to obtain a concentration of 1 milligram of cefaclor per milliliter.

(iii) *Calculations.* Calculate the cefaclor content as follows:

$$\text{Milligrams of cefaclor for 5 milliliters of sample} = \frac{A_u \times P_a \times d}{A_s \times 1,000}$$

where:

A_u =Absorbance of sample solution;

P_a =Potency of working standard in micrograms per milliliter;

A_s =Absorbance of working standard solution;

d =Dilution factor of the sample.

(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.

[46 FR 3833, Jan. 16, 1981; 46 FR 21360, Apr. 10, 1981, as amended at 47 FR 22515, May 25, 1982; 54 FR 41824, Oct. 12, 1989]

§ 442.106 Cefadroxil monohydrate oral dosage forms.

§ 442.106a Cefadroxil monohydrate capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefadroxil monohydrate capsules are composed of cefadroxil monohydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains either 250 or 500 milligrams of cefadroxil. Its moisture content is not more than 7.0 percent. The cefadroxil monohydrate used conforms to the standards prescribed by § 442.6(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 cefadroxil 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 cefadroxil monohydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.