

with sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter (estimated).

(c) *Calculations.* Calculate the cefadroxil content as follows:

$$\text{Milligrams per tablet} = \frac{A_u \times P_s \times d}{A_s \times 1,000 \times n}$$

where:

A_u =Absorbance of sample solution;
 P_s =Potency of working standard in micrograms per milligram;
 d =Dilution factor for sample;
 A_s =Absorbance of working standard solution;
 n =Number of tablets in the sample assayed.

(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.

[46 FR 2992, Jan. 13, 1981; 46 FR 15880, Mar. 10, 1981, as amended at 50 FR 19919, May 13, 1985; 54 FR 47352, Nov. 14, 1989]

§ 442.106c Cefadroxil monohydrate for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefadroxil monohydrate for oral suspension is cefadroxil monohydrate with one or more suitable and harmless preservatives, suspending agents, surfactants, binders, and flavorings. When reconstituted as directed in the labeling, each milliliter contains cefadroxil monohydrate equivalent to either 25, 50, or 100 milligrams of cefadroxil. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefadroxil 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 4.5 and not more than 6.0. 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, moisture, and pH.

(ii) Samples required:

(a) The cefadroxil 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.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric 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 cefadroxil per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 442.40(b)(1)(ii) of this chapter, except prepare the working standard and sample solutions and calculate the cefadroxil content as follows:

(a) *Preparation of working standard solution.* Dissolve and dilute an accurately weighed portion of the cefadroxil working standard in sufficient distilled water to a final concentration of 1 milligram of cefadroxil per milliliter.

(b) *Preparation of sample solution.* 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 to give a stock solution of convenient concentration.

Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter (estimated).

(c) *Calculations.* Calculate the cefadroxil content as follows:

$$\text{Milligrams per dose} = \frac{A_u \times P_s \times d}{A_s \times 1,000}$$

where:

A_u =Absorbance of sample solution;
 P_s =Potency of working standard in micrograms per milligram;
 d =Dilution factor for sample;
 A_s =Absorbance of working standard 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.

[46 FR 16679, Mar. 13, 1981, as amended at 50 FR 19919, May 13, 1985]

§ 442.107 Cefadroxil hemihydrate oral dosage forms.

§ 442.107a Cefadroxil hemihydrate capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefadroxil hemihydrate capsules are composed of cefadroxil hemihydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains cefadroxil hemihydrate equivalent to 500 milligrams of cefadroxil. Its cefadroxil content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefadroxil that it is represented to contain. Its moisture content is not more than 7.0 percent. It passes the dissolution test. The cefadroxil hemihydrate used conforms to the standards prescribed in § 442.7(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 hemihydrate used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

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

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

(A) The cefadroxil hemihydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 capsules.

(b) *Tests and methods of assay—(1) Cefadroxil content.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric 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 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. Remove an aliquot and further dilute with solution 1 to the reference concentration of 20 micrograms of cefadroxil per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay for cefadroxil.* Proceed as directed in § 442.40(b)(1)(ii), except prepare the working standard and sample solutions and calculate the potency of the sample as follows:

(A) *Preparation of working standard solutions.* Dissolve and dilute an accurately weighed portion of the cefadroxil working standard in sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter.

(B) *Preparation of sample solutions.* Blend a representative number of capsules in a high-speed glass blender jar with sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter (estimated).

(C) *Calculations.* Calculate the cefadroxil content as follows: