

$$\text{High molecular weight polymer content in percent} = \frac{H_u \times P_s \times 0.1}{H_s \times C_u}$$

where:

H_u =Height of the high molecular weight polymer peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

H_s =Mean height of the high molecular weight polymer peaks in the chromatograms of the high molecular weight polymer working standard;

P_s =High molecular weight polymer content of the high molecular weight polymer working standard solution in micrograms per milliliter; and

C_u =Milligrams of sample per milliliter of sample solution.

[50 FR 48399, Nov 25, 1985; 50 FR 53308, Dec. 31, 1985; 51 FR 2478, Jan. 17, 1986, as amended at 55 FR 11583, Mar. 29, 1990]

§ 442.17 Cefprozil sodium.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefprozil sodium is the sodium salt of [6*R*-[6 α , 7 β (*Z*)]-7-[(2,3-dihydro-2-imino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is so purified and dried that:

(i) Its cefprozil content is not less than 850 micrograms and not more than 995 micrograms of cefprozil per milligram on an anhydrous basis.

(ii) Its moisture content is not more than 8.5 percent.

(iii) Its pH in an aqueous solution containing 100 milligrams per milliliter is not less than 6.0 and not more than 8.0

(iv) It gives a positive identity test.

(v) It is crystalline.

(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 the batch for cefprozil content, moisture, pH, identity, and crystallinity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams, and 1 package containing approximately 5 grams.

(b) *Tests and methods of assay—(1) Cefprozil content.* Proceed as directed in § 436.345 of this chapter, preparing the sample solution and calculating the cefprozil content as described in paragraphs (e)(1) and (g)(1), respectively, of that section.

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

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 100 milligrams per milliliter.

(4) *Identity.* The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section, compares qualitatively to that of the cefprozil working standard.

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

[49 FR 49285, Dec. 19, 1984, as amended at 55 FR 11583, Mar. 29, 1990]

§ 442.17a Sterile cefprozil sodium.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefprozil sodium is the sodium salt of [6*R*-[6 α , 7 β (*Z*)]-7-[(2,3-dihydro-2-imino-4-thiazolyl)

(methoxyimino) acetyl]amino]-8-oxo-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylic acid. It is so purified and dried that:

(i) If the cefprozil is not packaged for dispensing, its cefprozil content is not less than 850 micrograms and not more than 995 micrograms of cefprozil per milligram on an anhydrous basis. If the cefprozil is packaged for dispensing, its cefprozil content is not less than 850 micrograms and not more than 995 micrograms of cefprozil per milligram on an anhydrous basis and also, each container contains not less than 90 percent and not more than 115 percent of the number of milligrams of cefprozil that it is represented to contain.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) Its moisture content is not more than 8.5 percent.

(v) Its pH in an aqueous solution containing 100 milligrams per milliliter is not less than 6.0 and not more than 8.0.

(vi) It gives a positive identity test.

(vii) It is crystalline.