

sample solution; and
m = Percent moisture content of the sample.

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens*. Proceed as directed in § 436.32(b) of this chapter, using a solution containing 20 milligrams of sulbactam per milliliter.

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

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

(6) *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 sulbactam working standard.

[52 FR 42290, Nov. 4, 1987; 52 FR 45281, Nov. 25, 1987, as amended at 54 FR 47205, Nov. 13, 1989; 55 FR 11585, Mar. 29, 1990]

§ 455.85 Vancomycin hydrochloride.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Vancomycin hydrochloride is the hydrochloride salt of a kind of vancomycin or a mixture of two or more such salts. It is soluble in water and moderately soluble in dilute methyl alcohol. It is insoluble in higher alcohols, acetone, and ether. It is so purified and dried that:

(i) It contains not less than 900 micrograms of vancomycin per milligram, calculated on an anhydrous basis.

(ii) [Reserved]

(iii) Its moisture content is not more than 5 percent.

(iv) Its pH in an aqueous solution containing 50 milligrams per milliliter is not less than 2.5 and not more than 4.5.

(v) It contains not more than 15 percent of factor A.

(vi) It gives a positive identity test for vancomycin.

(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 potency, moisture, pH, factor A content, and identity.

(ii) Samples required: 12 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay—(1) Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample of approximately 30 milligrams in sufficient sterile distilled water to give a stock solution of 1 milligram per milliliter (estimated). Further dilute an aliquot of the stock solution with 0.1M potassium phosphate buffer, pH 4.5 (solution 4), to the reference concentration of 10 micrograms of vancomycin per milliliter (estimated).

(2) [Reserved]

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

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using a solution containing 50 milligrams per milliliter.

(5) *Identity and factor A content*. Proceed as directed in § 455.85a(b)(7).

[39 FR 19166, May 30, 1974, as amended at 50 FR 19921, May 13, 1985]

§ 455.85a Sterile vancomycin hydrochloride.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Sterile vancomycin hydrochloride is the hydrochloride salt of a kind of vancomycin or a mixture of two or more such salts. It is soluble in water and moderately soluble in dilute methyl alcohol. It is insoluble in higher alcohols, acetone, and ether. It is so purified and dried that:

(i) It contains not less than 900 micrograms of vancomycin per milligram, calculated on an anhydrous basis. If it is packaged for dispensing, its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of vancomycin that it is represented to contain.

(ii) It is sterile.

(iii) [Reserved]

(iv) It is nonpyrogenic.

(v) Its moisture content is not more than 5 percent.

(vi) Its pH in an aqueous solution containing 50 milligrams per milliliter