

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

(2) *Related substances.* Proceed as directed in paragraph (b)(1) of this section for potency using the sample prepared as described in paragraph (b)(1)(ii)(B) of this section and calculating the amounts of related substances as follows.

(i) *Calculations.* Calculate the percentage of related substances as follows:

$$\text{Percent individual HPLC-related substance} = \frac{A_i \times 100}{A_t}$$

$$\text{Percent total HPLC-related substances} = \frac{A \times 100}{A_t}$$

where:

A_i = Area of the individual related substance peak;

A = The sum of areas of all peaks minus the area due to the rifabutin peak and solvent front peak; and

A_t = The sum of areas of all peaks in the chromatogram excluding the solvent peak.

(ii) [Reserved]

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

(4) *N-Isobutylpiperidone.* Proceed as directed in § 436.369 of this chapter.

(5) *Identity.* (i) Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(1) of that section using a 1 to 2 percent mixture in potassium bromide.

(ii) The identity of rifabutin is confirmed by the qualitative comparison of the HPLC of the sample to the rifabutin working standard as directed in paragraph (b)(1) of this section.

[59 FR 40807, Aug. 10, 1994; 59 FR 46479, Sept. 8, 1994]

§ 455.90a Sterile vidarabine monohydrate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Vidarabine monohydrate is the monohydrate form of 9-β - D - arabinofuranosyl - 9H - purin - 6-amine. It is a white to off-white powder. It is so purified and dried that:

(i) Its vidarabine content is not less than 845 micrograms and not more than 985 micrograms of vidarabine per milligram.

(ii) It is sterile.

(iii) [Reserved]

(iv) Its loss on drying is not less than 5 percent and not more than 7 percent.

(v) Its specific rotation in dimethylformamide at 25° C is −60.5°±4.5°.

(vi) It passes the identity test for vidarabine.

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5(b) of this chapter, this drug shall be labeled “vidarabine”.

(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 vidarabine content, sterility, loss on drying, specific rotation, and identity.

(ii) Samples required:

(a) For all tests except sterility: 10 packages, each containing approximately 500 milligrams.

(b) For sterility testing: 20 packages, each containing approximately 200 milligrams.

(b) *Tests and methods of assay—(1) Vidarabine content.* Proceed as directed in § 436.325 of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use 100 milligrams in lieu of 300 milligrams.

(3) [Reserved]

(4) *Loss on drying.* Proceed as directed in § 436.200(e) of this chapter.

(5) *Specific rotation.* Using a solution containing 10 milligrams of vidarabine per milliliter in dimethylformamide and a polarimeter tube 1.0 decimeter in length, proceed as directed in § 436.210 of this chapter, except determine the specific rotation at 365 nanometers.

(6) *Identity.* Proceed as directed in § 436.211 of this chapter, using the 0.5 percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

[42 FR 44224, Sept. 2, 1977; 43 FR 9802, Mar. 10, 1978, as amended at 44 FR 30334, May 25, 1979; 50 FR 19921, May 13, 1985]