

SOURCE: 39 FR 19166, May 30, 1974, unless otherwise noted.

Subpart A—Bulk Drugs

§ 455.4 Aztreonam.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Aztreonam is a practically odorless, white to slightly off-white fine powder. It is sparingly soluble in water of pH 2, and is very soluble at pH values above 4. Its solubility is slight to very slight in polar organic solvents such as methanol and ethanol and it is insoluble in nonpolar solvents such as hexane and heptane. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms of aztreonam per milligram on an "as is" basis.

(ii) Its moisture content is not more than 2.0 percent.

(iii) Its residue on ignition is not more than 0.1 percent.

(iv) Its heavy metals content is not more than 30 parts per million.

(v) It passes the identity test.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requirements 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, residue on ignition, heavy metals, and identify.

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

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 455.4a(b)(1).

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

(3) *Residue on ignition.* Proceed as directed in § 436.207(a) of this chapter.

(4) *Heavy metals.* Proceed as directed in § 436.208 of this chapter.

(5) *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, except prepare a solution containing 3 milligrams of aztreonam per milliliter of methanol

and use 0.5 milliliter of the solution as the sample.

[54 FR 40385, Oct. 2, 1989]

§ 455.4a Sterile aztreonam.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Aztreonam is a practically odorless, white to slightly off-white fine powder. It is sparingly soluble in water of pH 2, and is very soluble at pH values above 4. Its solubility is slight to very slight in polar organic solvents such as methanol and ethanol and it is insoluble in non-polar solvents such as hexane and heptane. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms of aztreonam per milligram on an "as is" basis.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) Its moisture content is not more than 2.0 percent.

(v) Its residue on ignition is not more than 0.1 percent.

(vi) Its heavy metals content is not more than 30 parts per million.

(vii) It passes the identity test.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requirements 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, sterility, pyrogens, moisture, residue on ignition, heavy metals, and identify.

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

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

(b) For sterility testing: 20 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.361 of this chapter, except in lieu of the guard column described in paragraph (a)(4) of that section, use a 5- to 10-centimeter precolumn having an inside diameter of 2 millimeters and packed with octadecyl silane chemically bonded to silica gel of a controlled surface porosity