

sample preparation described in paragraph (b)(1)(ii)(B) of this section should not be changed.

(iv) *Calculations*: Calculate the milligrams of aztreonam per milliliter of sample as follows:

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

where:

A_u =Area of the aztreonam peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s =Area of the aztreonam peak in the chromatogram of the working standard;

P_s =Aztreonam activity in the aztreonam working standard solution in micrograms per milliliter; and

d =Dilution factor 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, except inject a sufficient volume of the undiluted solution to deliver 50 milligrams of aztreonam per kilogram.

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

(5) *Identity*. The high-performance liquid chromatogram of the sample is determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the aztreonam working standard.

[54 FR 40385, Oct. 2, 1989]

§ 455.210 Chloramphenicol injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Chloramphenicol injection is chloramphenicol, with or without one or more suitable and harmless buffer substances, dissolved in one or more suitable and harmless solvents. Each milliliter contains 250 milligrams of chloramphenicol. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of chloramphenicol that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 4.7 and not more than 5.0. The chloramphenicol used conforms to

the standards prescribed by § 455.10a(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 chloramphenicol used in making the batch for potency, pH, specific rotation, melting range, absorptivity, and crystallinity.

(b) The batch for potency, sterility, pyrogens, and pH.

(ii) Samples required:

(a) The chloramphenicol used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of eight immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—(1) Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample in sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with distilled water to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except add the contents of each container directly to the dry filter, thus eliminating the preliminary solubilization step.

(3) *Pyrogens*. Proceed as directed in § 436.32(a) of this chapter, using a solution containing 5 milligrams per milliliter.

(4)–(5) [Reserved]

(6) *pH*. Proceed as directed in § 436.202 of this chapter, using the undiluted drug.

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