

Determine the end-point potentiometrically using a glass calomel combination electrode. Each milliliter of 0.1N sulfuric acid is equivalent to 8.401 milligrams of sodium bicarbonate.

(8) *Identity.* Using a 0.0025-percent solution of the sample in water and a suitable spectrophotometer, record the ultraviolet absorption spectrum from 220 to 310 nanometers. The spectrum compares qualitatively to that of the working standard similarly tested.

[40 FR 5355, Feb. 5, 1975, as amended at 46 FR 38503, July 28, 1981; 48 FR 51293, Nov. 8, 1983; 49 FR 5097, Feb. 10, 1984; 50 FR 19919, May 13, 1985]

§ 442.229 Sterile cephalixin sodium.

The requirements for certification and the tests and methods of assay for sterile cephalixin sodium packaged for dispensing are described in § 442.29a.

§ 442.240 Cephadrine injectable dosage forms.

§ 442.240a Cephadrine for injection.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cephadrine for injection is a dry mixture of cephadrine and one or more suitable and harmless solubilizing and buffering agents. Its potency is satisfactory if it contains not less than 90 percent and not more than 115 percent of the number of milligrams of cephadrine that it is represented to contain. It is sterile. It is nonpyrogenic. Its loss on drying is not more than 5.0 percent. Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 8.0 and not more than 9.6. The cephadrine used conforms to the standards prescribed by § 442.40a(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 sterile cephadrine used in making the batch for potency, moisture, pH, cephalixin content, identity, and crystallinity.

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

(ii) Samples required:

(a) The cephadrine used in making the batch: 10 packages, each containing approximately 500 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 10 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.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the sample as directed in the labeling for intramuscular use. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Further dilute an aliquot of this solution with solution 1 to the reference concentration of 10.0 micrograms of cephadrine per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 442.40(b)(1)(ii), preparing the sample as follows: Reconstitute the sample as directed in the labeling for intramuscular use. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Further dilute an aliquot of this solution with distilled water to 1 milligram of cephadrine 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.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 80 milligrams of cephadrine per milliliter.

(4) [Reserved]