

**§ 455.212 Sterile chloramphenicol sodium succinate.**

The requirements for certification and the tests and methods of assay for sterile chloramphenicol sodium succinate packaged for dispensing are described in § 455.12a.

[43 FR 9801, Mar. 10, 1978]

**§ 455.230 Moxalactam disodium for injection.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Moxalactam disodium for injection is a dry mixture of moxalactam disodium and mannitol. Its moxalactam content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of moxalactam that it is represented to contain. The moxalactam content of the dry mixture is not less than 722 micrograms of moxalactam per milligram. The ratio of R-isomer to S-isomer is not less than 0.8 and not more than 1.4. It is sterile. It is nonpyrogenic. Its moisture content is not more than 3.0 percent. Its pH is not less than 4.5 and not more than 7.0. It passes the identity test for moxalactam.

(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 moxalactam content, isomer ratio, sterility, pyrogens, moisture, pH, and identity.

(ii) Samples required on the batch:

(a) For all tests except sterility: A minimum of 10 immediate containers.

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

(b) *Tests and methods of assay—(1) Moxalactam content; isomer ratio.* Proceed as directed in § 436.332 of this chapter.

(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 solu-

tion containing 50 milligrams of moxalactam.

(4) [Reserved]

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

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 100 milligrams per milliliter.

(7) *Identity.* Proceed as directed in § 436.333 of this chapter.

[46 FR 61070, Dec. 15, 1981, as amended at 50 FR 19921, May 13, 1985]

**§ 455.251 Sodium novobiocin for injection.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Sodium novobiocin for injection is sodium novobiocin with or without one or more suitable solubilizing agents, preservatives, and diluents. Each vial contains 500 milligrams of novobiocin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of novobiocin that it is represented to contain. It is sterile and nonpyrogenic. Its loss on drying is not more than 6.0 percent. Its pH, when reconstituted as directed in the labeling, is not less than 6.5 and not more than 8.5. The sodium novobiocin used conforms to the standards prescribed by § 455.51a(a)(1) (i), (iii), (v), (vi), (vii), and (viii).

(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 the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The sodium novobiocin used in making the batch for potency, loss on drying, pH, residue on ignition, specific rotation, crystallinity, and identity.

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

(ii) Samples required:

(a) The sodium novobiocin 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*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Then 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. Dilute with 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 0.5 microgram of novobiocin 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 of this chapter, using a solution containing 10 milligrams of novobiocin per milliliter.

(4) [Reserved]

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

(6) *pH*. Proceed as directed in § 436.202 of this chapter, using the sample after reconstituting as directed in the labeling.

[39 FR 19166, May 20, 1974, as amended at 46 FR 25608, May 8, 1981; 50 FR 19921, May 13, 1985]

#### § 455.270 Rifampin for injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Rifampin for injection is a dry mixture of rifampin, sodium form-aldehyde sulfoxylate, and sodium hydroxide. Its potency is 600 milligrams per vial. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of rifampin that it is represented to contain. It is sterile. It is nonpyrogenic. Its moisture content is not more than 3.0 percent. Its pH is not less than 7.8 and not more than 8.8. It

passes the identity test. The rifampin used conforms to the standards prescribed by § 455.70(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 the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The rifampin used in making the batch for potency, loss on drying, pH, absorptivity, identity, and crystallinity.

(B) The batch for potency, sterility, pyrogens, moisture, pH, and identity.

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

(A) The rifampin 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*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove the withdrawable contents from each container represented as a single-dose container; or if the labeling specifies the amount of potency in a given volume of the preparation, withdraw an accurately measured volume from each container. Dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1) to give a stock solution of 1.0 milligram of rifampin per milliliter (estimated). Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 5.0 micrograms of rifampin 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 10 milligrams of rifampin per milliliter.