

**PART 453—LINCOMYCIN
ANTIBIOTIC DRUGS**

Subpart A—Bulk Drugs

- Sec.
453.20 Clindamycin hydrochloride hydrate.
453.21 Clindamycin palmitate hydrochloride.
453.22 Clindamycin phosphate.
453.22a Sterile clindamycin phosphate.
453.30 Lincomycin hydrochloride monohydrate.
453.30a Sterile lincomycin hydrochloride monohydrate.

Subpart B—Oral Dosage Forms

- 453.120 Clindamycin hydrochloride hydrate capsules.
453.121 Clindamycin palmitate hydrochloride oral dosage forms.
453.121a Clindamycin palmitate hydrochloride for oral suspension.
453.121b Clindamycin palmitate hydrochloride for oral solution.
453.130 Lincomycin hydrochloride oral dosage forms.
453.130a Lincomycin hydrochloride monohydrate capsules.
453.130b Lincomycin hydrochloride syrup.

Subpart C—Injectable Dosage Forms

- 453.222 Clindamycin phosphate injection.
453.230 Lincomycin hydrochloride injection.

Subparts D–E [Reserved]

Subpart F—Dermatologic Dosage Forms

- 453.522 Clindamycin phosphate dermatologic dosage forms.
453.522a Clindamycin phosphate topical solution.
453.522b Clindamycin phosphate gel.
453.522c Clindamycin phosphate lotion.
453.522d Clindamycin phosphate vaginal cream.

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Subpart A—Bulk Drugs

§ 453.20 Clindamycin hydrochloride hydrate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin hydrochloride hydrate is the hydrated hydrochloride salt of clindamycin. It is so purified and dried that:

(i) Its clindamycin content is not less than 800 micrograms of clindamycin per milligram.

(ii) Its microbiological activity is not less than 800 micrograms of clindamycin per milligram.

(iii) [Reserved]

(iv) Its moisture content is not less than 3.0 percent and not more than 6.0 percent.

(v) Its pH in an aqueous solution containing 100 milligrams per milliliter is not less than 3.0 and not more than 5.5.

(vi) It is crystalline.

(vii) It passes the identity test for clindamycin hydrochloride hydrate.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5(b) 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 clindamycin content, microbiological activity, moisture, pH, crystallinity, and identity.

(ii) Samples required: 10 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay*—(1) *Clindamycin content (vapor phase chromatography).* Proceed as directed in § 436.302 of this chapter.

(2) *Microbiological activity (microbiological agar diffusion assay.)* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient sterile distilled water to give a stock solution of convenient concentration. Further dilute the stock solution with 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of clindamycin per milliliter (estimated).

(3) [Reserved]

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

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

(6) *Crystallinity.* Proceed as directed in § 436.203 of this chapter.

(7) *Identity.* Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(2) of that section.

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