

and purity. Nystatin topical powder is a dry powder composed of nystatin and talc. Each gram contains 100,000 units of nystatin. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of nystatin that it is represented to contain. Its loss on drying is not more than 2.0 percent. The nystatin used conforms to the standards prescribed by § 449.50(a)(1) (i), (iii), (iv), and (v).

(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 nystatin used in making the batch for potency, loss on drying, pH, and identity.

(b) The batch for potency and loss on drying.

(ii) Samples required:

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

(b) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend an accurately weighed representative sample for 3 to 5 minutes in a high-speed glass blender with sufficient dimethylformamide to give a convenient concentration. Dilute with sufficient dimethylformamide to yield a stock solution containing 400 units of nystatin per milliliter (estimated). Further dilute with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

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

§ 449.550g Nystatin-neomycin sulfate-gramicidin topical powder.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Nystatin-neomycin sulfate-gramicidin topical powder is a dry powder composed of nystatin, neomycin sulfate, gramicidin, and talc. Each gram contains 100,000 units of nystatin,

2.5 milligrams of neomycin and 0.25 milligram of gramicidin. Its nystatin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of nystatin that it is represented to contain. Its neomycin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin that it is represented to contain. Its gramicidin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of gramicidin that it is represented to contain. Its loss on drying is not more than 2.0 percent. The nystatin used conforms to the standards prescribed by § 449.50(a)(1) (i), (iii), (iv), and (v). The neomycin sulfate used conforms to the standards prescribed by § 444.42a(a)(1) of this chapter. The gramicidin used conforms to the standards prescribed by § 448.25(a)(1) (i), (iii), (iv), (v) and (vi) of this chapter.

(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 nystatin used in making the batch for potency, loss on drying, pH, and identity.

(b) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identity.

(c) The gramicidin used in making the batch for potency, loss on drying, residue on ignition, melting point, crystallinity, and identity.

(d) The batch for nystatin content, neomycin content, gramicidin content, and loss on drying.

(ii) Samples required:

(a) The nystatin used in making the batch: 10 packages each consisting of 300 milligrams.

(b) The neomycin sulfate used in making the batch: 10 packages, each consisting of 300 milligrams.

(c) The gramicidin used in making the batch: 10 packages, each consisting of 500 milligrams.

(d) The batch: A minimum of seven immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Nystatin content*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend the entire contents of an accurately weighed representative portion of the sample for 3 to 5 minutes in a high-speed glass blender with sufficient dimethylformamide to give a convenient concentration. Dilute with sufficient dimethylformamide to yield a stock solution containing 400 units of nystatin per milliliter (estimated). Further dilute with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

(ii) *Neomycin content*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend an accurately weighed representative sample for 3 to 5 minutes in sufficient 0.1M potassium phosphate buffer, pH 8 (solution 3), to give a convenient concentration. Further dilute an aliquot with solution 3 to the reference concentration of 1 microgram of neomycin per milliliter (estimated).

(iii) *Gramicidin content*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed representative sample in alcohol U.S.P. XX and filter. Collect the filtrate and dilute a portion with alcohol U.S.P. XX to the reference concentration of 0.04 microgram of gramicidin per milliliter (estimated).

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

[39 FR 19134, May 30, 1974, as amended at 41 FR 10886, Mar. 15, 1976; 47 FR 23710, June 1, 1982; 50 FR 19920, May 13, 1985]

§ 449.550h Nystatin lotion.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Nystatin lotion is composed of nystatin with one or more suitable and harmless suspending agents, emulsifiers, surfactants, and preservatives in a suitable and harmless vehicle. Each milliliter contains 100,000 units of nystatin. Its potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of nystatin that it is represented to contain. Its pH is not less than 5.5

and not more than 7.5. The nystatin used conforms to the standards prescribed by § 449.50(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 nystatin used in making the batch for potency, loss on drying, pH, and identity.

(b) The batch for potency and pH.

(ii) Samples required:

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

(b) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately measured representative portion of the sample into a high-speed glass blender jar containing sufficient dimethylformamide to give a convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and dilute with sufficient dimethylformamide to yield a stock solution containing 400 units of nystatin per milliliter (estimated). Further dilute with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

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

[40 FR 3766, Jan. 24, 1975, as amended at 50 FR 19920, May 13, 1985]

Subpart G—Vaginal Dosage Forms

§ 449.610 Candididin vaginal dosage forms.

§ 449.610a Candididin vaginal ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Candididin vaginal ointment is composed of candididin and a suitable ointment base. It contains 0.6 milligram of candididin per gram. Its