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Nystatin Vaginal Inserts

DEFINITION

Nystatin Vaginal Inserts are composed of Nystatin with suitable binders, diluents, and lubricants. Vaginal Inserts contain NLT 90.0% and NMT 140.0% of the labeled amount of USP Nystatin Units.

ASSAY

• **Nystatin**

(See *Antibiotics—Microbial Assays* ⟨81⟩.)

Sample stock solution: 400 USP Nystatin Units/mL in dimethylformamide prepared as follows. Blend NLT 5 Vaginal Inserts for 3–5 min in a high-speed blender with a sufficient volume of dimethylformamide to obtain a solution of suitable concentration. Dilute a portion of this solution with dimethylformamide.

Test dilution: Dilute a volume of the *Sample stock solution* with *Buffer B.6* to obtain a nystatin concentration assumed to be equal to the median dose level of the standard.

Acceptance criteria: 90.0%–140.0% of the labeled amount of USP Nystatin Units

PERFORMANCE TESTS

• **Disintegration** ⟨701⟩

Time: 60 min

Analysis: Use the *Procedure* for *Uncoated Tablets* in the chapter.

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩**:** Dry 100 mg of powdered Vaginal Inserts in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h: it loses NMT 5.0% of its weight.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers and, where so specified in the labeling, in a refrigerator.

• **USP Reference Standards** ⟨11⟩

USP Nystatin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NYSTATIN VAGINAL INSERTS	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

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