Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-24D42270-6742-49B4-9D68-F07AA97A3534_1_en-US
DOI: https://doi.org/10.31003/USPNF_M58130_01_01
DOI Ref: py875

Nystatin Tablets

DEFINITION
Nystatin Tablets contain NLT 90.0% and NMT 130.0% of the labeled amount of USP Nystatin Units.

ASSAY
• **Procedure**

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

Sample solution: 400 USP Nystatin Units/mL prepared as follows. Blend NLT 5 Tablets 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.

Analysis: Proceed as directed in the chapter. Dilute an aliquot of the *Sample solution* with *Buffer B.6* to obtain a *Test Dilution* having a nystatin concentration assumed to be equal to the median level of the standard.

Acceptance criteria: 90.0%–130.0% of the labeled amount of USP Nystatin Units

PERFORMANCE TESTS
• **Disintegration** ⟨701⟩

Time: If plain-coated, 120 min

Acceptance criteria: Meet the requirements

SPECIFIC TESTS
• **Loss on Drying** ⟨731⟩

Sample: 100 mg of powdered Tablets

Analysis: Dry the *Sample* in a capillary-stoppered bottle under vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h.

Acceptance criteria: If plain-coated, NMT 5.0%; if film-coated, NMT 8.0%

ADDITIONAL REQUIREMENTS
• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **Labeling:** Label the Tablets to indicate that they are intended for oral use only (as distinguished from Vaginal Tablets).

• **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 TABLETS	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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 28(1)

Current DocID: GUID-24D42270-6742-49B4-9D68-F07AA97A3534_1_en-US

DOI: https://doi.org/10.31003/USPNF_M58130_01_01

DOI ref: py875