

Status: Currently Official on 16-Feb-2025  
 Official Date: Official Prior to 2013  
 Document Type: USP Monographs  
 DocId: GUID-6BF1FB0F-70DF-4F6A-8840-43D03A36E17E\_1\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M58121\\_01\\_01](https://doi.org/10.31003/USPNF_M58121_01_01)  
 DOI Ref: e4e15

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## Nystatin for Oral Suspension

### DEFINITION

Nystatin for Oral Suspension is a dry mixture of Nystatin with one or more suitable colors, diluents, suspending agents, flavors, and preservatives. It contains the equivalent of NLT 90.0% and NMT 140.0% 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. Constitute Nystatin for Oral Suspension as directed in the labeling. Blend a suitable aliquot of the suspension, freshly mixed and free from air bubbles, 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 the resulting 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%–140.0% of the labeled amount of USP Nystatin Units

### PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#)

**For powder packaged in single-unit containers**

**Acceptance criteria:** Meets the requirements

- [DELIVERABLE VOLUME \(698\)](#)

**For powder packaged in multiple-unit containers**

**Acceptance criteria:** Meets the requirements

### SPECIFIC TESTS

- [pH \(791\)](#)

**Sample suspension:** Constitute as directed in the labeling.

**Acceptance criteria:** 4.9–5.5

- [WATER DETERMINATION, Method I \(921\)](#): NMT 7.0%

### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [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 FOR ORAL SUSPENSION	<a href="#">Ying Han</a> Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	BIO42020 Biologics Monographs 4 - Antibiotics

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. PF 30(1)

**Current DocID: GUID-6BF1FB0F-70DF-4F6A-8840-43D03A36E17E\_1\_en-US**

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