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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	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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