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Nystatin Oral Suspension

» Nystatin Oral Suspension contains not less than 90.0 percent and not more than 130.0 percent of the labeled amount of USP Nystatin Units. It contains suitable dispersants, flavors, preservatives, and suspending agents.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—
USP Nystatin RS

Uniformity of dosage units ⟨905⟩—
FOR SUSPENSION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.
Procedure for content uniformity—[Note—Use low-actinic glassware.] Transfer the well-shaken contents of 1 container of Oral Suspension to a 100-mL volumetric flask, dissolve in and dilute with methanol to volume, and mix. Dilute an accurately measured volume of this solution quantitatively, and stepwise if necessary, with methanol to obtain a test solution containing about 25 USP Nystatin Units per mL. Similarly, prepare a Standard solution of USP Nystatin RS in methanol having a known concentration of about 25 USP Nystatin Units per mL. Concomitantly determine the absorbances of the test solution and the Standard solution at the wavelength of maximum absorbance at about 304 nm with a suitable spectrophotometer, using methanol as the blank. Calculate the quantity, in USP Nystatin Units, in the container taken by the formula:

$$(CL/D)(A_U/A_S)$$

in which C is the concentration, in USP Nystatin Units per mL, of the Standard solution; L is the labeled quantity, in USP Nystatin Units, in the container; D is the concentration, in USP Nystatin Units, in the test solution, on the basis of the labeled quantity in the container and the extent of dilution; and A_U and A_S are the absorbances of the test solution and the Standard solution, respectively.

Deliverable volume ⟨698⟩: meets the requirements.

pH ⟨791⟩: between 4.5 and 6.0; or if it contains glycerin, between 5.3 and 7.5.

Assay—Proceed as directed for Nystatin under *Antibiotics—Microbial Assays ⟨81⟩*, blending a suitable accurately measured volume of Oral Suspension, freshly mixed and free from air bubbles, for 3 to 5 minutes in a high-speed blender with a sufficient accurately measured volume of dimethylformamide to obtain a solution of convenient concentration. Dilute an accurately measured portion of this solution quantitatively with dimethylformamide to obtain a stock solution containing about 400 USP Nystatin Units per mL. Dilute this stock solution quantitatively with *Buffer B.6* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
NYSTATIN 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

Chromatographic Database Information: Chromatographic Database

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