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Nystatin Cream

DEFINITION
Nystatin Cream contains 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 a suitable portion of Cream in a high-speed blender for 3–5 min with a suitable volume of 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

- MINIMUM FILL (755):** Meets the requirements

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE:** Preserve in collapsible tubes, or in other tight containers, and avoid exposure to excessive heat.
- 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 CREAM	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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