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Nystatin Lozenges

» Nystatin Lozenges contain not less than 90.0 percent and not more than 125.0 percent of the labeled amount of USP Nystatin Units.

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

USP Reference standards ⟨11⟩—

USP Nystatin RS

Disintegration ⟨701⟩: 90 minutes, determined as set forth under *Uncoated Tablets*.

pH ⟨791⟩: between 5.0 and 7.5, in a solution prepared by dissolving 1 Lozenge in 100 mL of water at 37° and allowing the solution to cool to room temperature.

Assay—Proceed as directed for Nystatin under *Antibiotics—Microbial Assays* ⟨81⟩, blending not less than 5 Lozenges for 18 to 20 minutes in a high-speed blender jar containing 100.0 mL of water. Add 400.0 mL of dimethylformamide, and blend for an additional 10 minutes. Dilute an accurately measured volume of this solution quantitatively with a mixture of dimethylformamide and water (4:1) to obtain a stock solution containing about 400 USP Nystatin Units per mL. Dilute an accurately measured volume of this stock solution quantitatively with *Buffer B.6* to obtain a *Test Dilution* having a nystatin concentration assumed to be equal to the median dose level of the Standard. [Note—The *Test Dilution* of the specimen and the test dilutions of the Standard contain the same amount of dimethylformamide (about 4%).]

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

Topic/Question	Contact	Expert Committee
NYSTATIN LOZENGES	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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