

NYSTATINUM 5 g
Lot No.: 25D24-F250229

Authorisation:	1890R05431	Date Of Analysis:	11/03/2025
Analytical Reference:	Ph. Eur. [01/2019:0517]	Production Number:	070525-G240309
CNK:	3490679	Expiry Date:	09/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Yellow or slightly brownish powder, hygroscopic	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with nystatin CRS	Complies
Identification E	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a)	Complies
TESTS	SPECIFICATION	RESULT
Absorbance	A _{305 nm} ≥ 0.60	0.76
Composition		
Nystatin A1	≥ 85.0%	91.9%
Any other compound	≤ 4.0%	Complies
Loss on drying	≤ 5.0%	0.9%
Sulfated ash	≤ 3.5%	0.5%
ASSAY	SPECIFICATION	RESULT
Microbiological assay of antibiotics	≥ 5000 IU/mg (dried substance)	5297 IU/mg

Manufacturer identification code: S/GS/044

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: