



CERTIFICATE OF ANALYSIS

Product : NYSTATIN
Product number : N0138
Batch number : 018837
Date of production : xx-03-2023
Date of analysis : 03-08-2023
Date of expiry : 31-03-2026

Packaging and storage : store in a well-closed container, protected from light at a temperature of 2 – 8 °C

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	yellow or slightly brownish powder	complies		hygroscopic
Identification:				
- B (IR-spectrum)	conform	complies		
- E (retention time HPLC)	conform	complies		
UV-absorbance	≥ 0.60	0.81		
Composition:	conform	complies		
- Nystatin A1	≥ 85.0	93.7	%	
- Any other compound	≤ 4.0	2.3	%	
Loss on drying	≤ 5.0	3.1	%	
Sulphated ash	≤ 3.5	0.8	%	
Assay	≥ 5000	5670	IE/mg	dried substance

This certificate of analysis is conform the results of the supplier.

Conclusion: approved

Released by:

J. van der Eem, pharmacist
Department of Quality Control Duchefa B.V.

Date: 18-10-2024

The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.

