

CERTIFICATE OF ANALYSIS

Product : NYSTATIN
Product number : N0138
Batch number : 017402
Date of production : xx-11-2021
Date of analysis : 01-02-2022
Date of expiry : 30-11-2023

Packaging and storage

store in a well-closed container, protected from light at a temperature of 2-8 °C

Appearance	SPECIFICATION yellow or slightly brownish powder	RESULT complies	UNITS	REMARKS hygroscopic
Identification:				
- B (IR-spectrum)	conform	complies		
- E (retention time HPLC)	conform	complies		
UV-absorbance	≥ 0.60	0.86		max. 305 nm
Composition:				HPLC
- Nystatin A1	≥ 85.0	95.8	%	
- Any other compound	each ≤ 4.0	1.6	%	
Loss on drying	≤ 5.0	3.2	%	3h, P ₂ O ₅ , 60 °C, < 0.1 kPa
Sulphated ash	≤ 3.5	0.8	%	-,
Assay	≥ 5000	5483	IU/mg	dried substance

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

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist

Department of Quality Control Duchefa B.V.

Date: 11-11-2022

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

Duchefa Biochemie B.V.