



CERTIFICATE OF ANALYSIS

Product : **NYSTATIN**
Product number : N0138
Batch number : 015788
Date of production : xx-11-2019
Date of analysis : 29-05-2020
Date of expiry : 30-11-2021

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		max. 305 nm HPLC
Composition:				
- Nystatin A1	≥ 85.0	93.2	%	
- Any other compound	each ≤ 4.0	< 1.7	%	
Loss on drying	≤ 5.0	1.4	%	3h, P ₂ O ₅ , 60 °C, < 0.1 kPa
Sulphated ash	≤ 3.5	0.8	%	
Assay	≥ 5000	6678	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: 29-10-2020

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

Duchefa Biochemie B.V.

