

CERTIFICATE OF ANALYSIS

Product : **NYSTATIN**
Product number : **N0138**
Batch number : **013916**
Date of analysis : **14-03-2018**
Date of expiry : **31-01-2020**

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	0.824		max. 305 nm
Composition:				HPLC
- Nystatin A1	≥ 85.0	91.16	%	
- Any other compound	each ≤ 4.0	each < 1.78	%	
Loss on drying	≤ 5.0	3.81	%	3h, P ₂ O ₅ , 60 °C, < 0.1 kPa
Sulphated ash	≤ 3.5	0.7	%	
Assay	≥ 5000	6485	IU/mg	dried substance

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

Conclusion: approved

Released by:



Date: 19-07-2018

drs. Q. de Hoog, pharmacist
Department of Quality Control Duchefa B.V.

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