

## CERTIFICATE OF ANALYSIS

Product : **NYSTATIN**  
Product number : **N0138**  
Batch number : **011659**  
Date of analysis : **28-10-2015**  
Date of expiry : **31-10-2017**

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

	<b>SPECIFICATION</b>	<b>RESULT</b>	<b>UNITS</b>	<b>REMARKS</b>
Appearance	yellow or slightly brownish powder	complies		hygroscopic
Identity:				
- B (IR-spectrum)	conform	complies		
- E (retention time HPLC)	conform	complies		
UV-absorbance	≥ 0.60	0.80		max. 305 nm
Composition:				HPLC
- Nystatin A1	≥ 85.0	91.83	%	
- Any other compound	≤ 4.0	< 4.0	%	
Heavy metals	≤ 20	< 20	ppm	as Pb
Loss on drying	≤ 5.0	0.60	%	3h, P <sub>2</sub> O <sub>5</sub> , 60 °C, < 0.1 kPa
Sulphated ash	≤ 3.5	0.82	%	
Abnormal toxicity	conform	complies		
Assay	≥ 5000	6058	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: 18-11-2015



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