

CERTIFICATE OF ANALYSIS

Product : **NYSTATIN**
Product number : N0138
Batch number : 012487
Date of analysis : 29-09-2016
Date of expiry : 30-09-2018

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
Identity:				
- B (IR-spectrum)	conform	complies		
- E (retention time HPLC)	conform	complies		
UV-absorbance	≥ 0.60	0.83		max. 305 nm
Composition:				HPLC
- Nystatin A1	≥ 85.0	89.93	%	
- Any other compound	≤ 4.0	3.24	%	
Heavy metals	≤ 20	< 20	ppm	as Pb
Loss on drying	≤ 5.0	4.2	%	3h, P ₂ O ₅ , 60 °C, < 0.1 kPa
Sulphated ash	≤ 3.5	1.4	%	
Assay	≥ 5000	6292	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: 31-10-2016



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