

CERTIFICATE OF ANALYSIS

Product : **NYSTATIN**
Product number : **N0138**
Batch number : **013097**
Date of analysis : **08-03-2017**
Date of expiry : **31-03-2019**

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	0.88		max. 305 nm
Composition:				HPLC
- Nystatin A1	≥ 85.0	92.4	%	
- Any other compound	≤ 4.0	each < 2.0	%	
Heavy metals	≤ 20	< 20	ppm	as Pb
Loss on drying	≤ 5.0	3.49	%	3h, P ₂ O ₅ , 60 °C, < 0.1 kPa
Sulphated ash	≤ 3.5	0.6	%	
Assay	≥ 5000	6228	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: 26-07-2017



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