

CERTIFICATE OF ANALYSIS

Product **NYSTATIN** Product number N0138 Batch number 012487 29-09-2016 Date of analysis 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

Appearance	SPECIFICATION yellow or slightly brownish powder	RESULT complies	UNITS	REMARKS 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_2O_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.

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