

## CERTIFICATE OF ANALYSIS

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

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

Appearance Identity:	SPECIFICATION yellow or slightly brownish powder	RESULT complies	UNITS	REMARKS hygroscopic
- 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, $P_2O_5$ , 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.

telephone: +31(0)23 - 531 90 93 iban: NL54 INGB 0651 4661 80 k.v.k. in Amsterdam: 34073001 mail address: Postbus 809 - 2003 RV Haarlem - The Netherlands +31(0)23 - 531 80 27 bic: INGBNL2A website: www.duchefa.com visiting address: A. Hofmanweg 71 - 2031 BH Haarlem telefax: info@duchefa.nl

e-mail: