

CERTIFICATE OF ANALYSIS

Product NYSTATIN Product number N0138 Batch number 015437 Date of analysis 17-02-2020 Date of expiry 28-02-2022

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
Identification:				
- B (IR-spectrum)	conform	complies		
- E (retention time HPLC)	conform	complies		
UV-absorbance	≥ 0.60	0.82		max. 305 nm
Composition:				HPLC
- Nystatin A1	≥ 85.0	93.8	%	
- Any other compound	each ≤ 4.0	each < 2.7	%	
Loss on drying	≤ 5.0	0.5	%	3h, P ₂ O ₅ , 60 °C, < 0.1 kPa
Sulphated ash	≤ 3.5	0.7	%	
Assay	≥ 5000	6577	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: 14-05-2020

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