Certificate of Analysis

Product name: **Nystatinum**

Batch number / Weight: **21H13-B01-216750 / 5 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow or slightly brown powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform	%	
Specific absorbance	>= 0,60	0,839		
Composition	Conform	Conform		
Nystatin A1	>= 85,0	93,75	% m/m	
Any other compound	<= 4,0	1,80	%	
Loss on drying	<= 5,0	2,79	%	
Sulphated ash	<= 3,5	0,03	%	
Assay (oral)	>=5000 (dried substance)	5884	IU/mg	
	>=4400 (as is)	5720	IU/mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

30-03-2022

Expiration: 31-07-2024

Conclusion: APPROVED

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