Certificate of Analysis

Product name: **Nystatinum**

Batch number / Weight: **21C01-B01-210106 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow or slightly brown powder	Conform		
Identification	Conform	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform	%	
Solubility	acc. to Ph. Eur.	Conform		
Specific absorbance	>= 0,60	0,781		
Composition	Conform	Conform		
Nystatin A1	>= 85,0	92,29	% m/m	
Any other compound	<= 4,0	2,76	%	
Loss on drying	<= 5,0	1,38	%	
Sulphated ash	<= 3,5	0,79	%	
Assay	>=4400	6240	IU/mg	
	>=4400 (as is)	6154	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:
Agnieszka Pszczółka
Qualified Person

15-04-2021

Expiration: 29-02-2024

Conclusion: APPROVED

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