Certificate of Analysis

Product name: **Nystatinum**

Batch number / Weight: **22D27-B05-223309 / 5 G**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22D27-B05 / INS-22-5252**

Reference Code / No.: **V00753 / 11000422A**

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	%	
Specific absorbance	>= 0,60	0,789		
Composition	Conform	Conform		
Nystatin A1	>= 85,0	89,23	% m/m	
Any other compound	<= 4,0	2,53	%	
Loss on drying	<= 5,0	3,18	%	
Sulphated ash	<= 3,5	1,27	%	
Assay (oral)	>=5000 (dried substance)	6547	IU/mg	
Assay	>=4400	6547	IU/mg	
	>=4400 (as is)	6339	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		
Residual solvents				
Methanol	not more than 3000	188	ppm	
Acetone	not more than 5000	252	ppm	
Buthanol	not more than 1000	32	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, HASCO, CBM

Release:
Agnieszka Pszczółka
Qualified Person

13-09-2022

Expiration: 31-03-2025

Conclusion: APPROVED

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