Certificate of Analysis

Product name: **Nystatinum**

Batch number / Weight: **22L08-B04-230503 / 25 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **22L08-B04 / INS-23-0685**

Reference Code / No.: **V00753 / 35701122**

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		
Solubility	acc. to Ph. Eur.	Conform		
Specific absorbance	>= 0,60	0,854		
Composition	Conform	Conform		
Nystatin A1	>= 85,0	89,89	% m/m	
Any other compound	<= 4,0	2,37	%	
Loss on drying	<= 5,0	0,74	%	
Sulphated ash	<= 3,5	1,35	%	
Assay (oral)	>=5000 (dried substance)	6479	IU/mg	
Assay	>=4400	6479	IU/mg	
	>=4400 (as is)	6431	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		
Total aerobic microbial count (TA		<1	CFU/g	
Total yeasts and moulds (TYMC)		<1	CFU/g	
Residual solvents				
Methanol	<= 3000	<3000	ppm	
Acetone	<5000 ppm	<5000	ppm	
Buthanol	<= 5000	<5000	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, CBMiA

Release:
Dominika Sołtysik
Qualified Person

17-05-2023

Expiration: 31-10-2025

Conclusion: APPROVED

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