

Certificate of Analysis

Product name: **Nystatinum**

Batch number / Weight: **22A18-B07-219909 / 25 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	$\geq 0,60$	0,865		
Composition	Conform	Conform		
Nystatin A1	$\geq 85,0$	89,94	% m/m	
Any other compound	$\leq 4,0$	2,21	%	
Loss on drying	$\leq 5,0$	0,90	%	
Sulphated ash	$\leq 3,5$	0,81	%	
Assay	≥ 4400	6537	IU/mg	
	≥ 4400 (as is)	6478	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	≤ 3000	<3000	ppm	
Acetone	<5000 ppm	<5000	ppm	
Buthanol	≤ 5000	<5000	ppm	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

16-05-2022

Expiration: 31-12-2024

Conclusion: APPROVED

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