

Certificate of Analysis

Product name: **Nystatinum**
Batch number / Weight: **21H13-B01-214387 / 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	$\geq 0,60$	0,839		
Composition	Conform	Conform		
Nystatin A1	$\geq 85,0$	93,75	% m/m	
Any other compound	$\leq 4,0$	1,80	%	
Loss on drying	$\leq 5,0$	2,79	%	
Sulphated ash	$\leq 3,5$	0,03	%	
Assay (oral)	≥ 5000 (dried substance)	5884	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	23	ppm	
Acetone	not more than 5000	43	ppm	
Buthanol	not more than 1000	15	ppm	

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

09-12-2021

Expiration: 31-07-2024

Conclusion: APPROVED

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