

Certificate of Analysis

Product name: Nystatinum
Batch number / Weight: 19H08-B03-195655 / 25 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow or slightly brown powder	Conform		
Identification B	Conform	Conform		
Identification E	Conform	Conform		
Absorbance	$\geq 0,60$	0,787		
Composition	Conform	Conform		
Nystatin A1	$\geq 85,0$	89,18	%m/m	
Any other compound	$\leq 4,0$	2,42	%	
Loss on drying	$\leq 5,0$	3,32	%	
Sulphated ash	$\leq 3,5$	1,43	%	
Assay Nystatin	≥ 5000	6644	IU/mg	
Assay		6424	IU/mg	
Abnormal toxicity	Conform	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

08-01-2020

Expiration: 30-06-2022

Conclusion: APPROVED

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