



Version 2

**Certificate of Analysis**

**Product name:** Nystatinum  
**Batch number:** 18K26-B01-190108  
**Base unit:** 25g  
**Expiration date:** 30.11.2021  
**Quality:** Ph.Eur.  
**Manufacturing date:** 15.01.2019  
**Inspection report no.:** INS-19-00067  
**INN:** 100827-114-91

Description	Claim	Result	Unit	Standard remark
Appearance	Yellow or slightly brownish powder, hygroscopic	conform		
Identification B	acc. to Ph. Eur.	conform		
Identification E	acc. to Ph. Eur.	conform		
Absorbance	$\geq 0,60$	conform		
Composition:				
Nystatin A1	$\geq 85,0\%$	91,19	%	
Any other compound	$\leq 4,0\%$	3,46	%	
Loss on drying	$\leq 5,0\%$	3,29	%	Hasco Lek
Sulphated ash	$\leq 3,5\%$	1,57	%	
Assay	$\geq 4400$ IU/mg (dried substance)	6783	IU/mg	Hasco Lek
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 laboratory Fagron Poland and Hasco Lek.

Release:  
Aleksandra Mazanek  
Qualified Person

Date of releasing: 19.01.2019

Conclusion: Approved



Fagron sp. z o.o.  
*Aleksandra Mazanek*  
Aleksandra Mazanek  
osoba wykwalifikowana

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