

Certificate of Analysis

Product name: Nystatinum
Batch number: 20H18-B13-201990
Base unit: 25g
Expiration date: 31.07.2023
Quality: Ph. Eur.
Manufacturing date: 07.09.2020
Inspection report no.: INS-20-03866
INN: 100827-114-91

Description	Claim	Result	Unit	Laboratory
Appearance	Yellow or slightly brownish powder, hygroscopic	conform		Fagron Poland
Identification B	acc. to Ph. Eur.	conform		Fagron Poland
Identification E	acc. to Ph. Eur.	conform		Fagron Poland
Absorbance	$\geq 0,60$	0,738		Fagron Poland
Composition:				
Nystatin A1	$\geq 85,0\%$	87,88	%	Fagron Poland
Any other compound	$\leq 4,0\%$	3,67	%	Fagron Poland
Loss on drying	$\leq 5,0\%$	1,93	%	Fagron Poland
Sulphated ash	$\leq 3,5\%$	1,34	%	Fagron Poland
Assay	≥ 4400 IU/mg (dried substance)	6566 6439 „as is”	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: Hasco Lek and Fagron Poland.

Release:
 Ewelina Gadzinowska
 Qualified Person

Fagron sp. z o.o.
Ewelina Gadzinowska
 osoba wykwalifikowana
 qualified person

Date of releasing: 05.10.2020

Conclusion: Approved