

Certificate of Analysis

Product name: Nystatinum
Batch number: 20L29-B07-203492
Base unit: 25g
Expiration date: 30.11.2023
Quality: Ph. Eur.
Manufacturing date: 31.03.2021
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	$\geq 0,60$	0,851		Fagron Poland
Composition:				
Nystatin A1	$\geq 85,0\%$	92,73	%	Fagron Poland
Any other compound	$\leq 4,0\%$	2,31	%	Fagron Poland
Loss on drying	$\leq 5,0\%$	3,79	%	Fagron Poland
Sulphated ash	$\leq 3,5\%$	1,13	%	Fagron Poland
Assay	≥ 4400 IU/mg (dried substance)	5076 4884 „as is”	IU/mg	EL spol
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:

Dominika Sottysik

Qualified Person

Fagron sp. z o.o.

Dominika Sottysik
osoba wykwalifikowana
qualified person

Date of releasing: 14.04.2021

Conclusion: Approved