Fagron
personalizing medicine

Certificate of Analysis

Product name: Nystatinum
Batch number: 20H18-B13-203385
Base unit: 5g
Expiration date: 31.07.2023
Quality: Ph. Eur.
Manufacturing date: 10.11.2020
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	≥ 0,60	0,738		Fagron Poland
Composition:				
Nystatin A1	≥ 85,0%	87,88	%	Fagron Poland
Any other compound	≤ 4,0%	3,67	%	Fagron Poland
Loss on drying	≤ 5,0%	1,93	%	Fagron Poland
Sulphated ash	≤ 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: 23.11.2020

Conclusion: Approved