

Certificate of Analysis

Product name: **Nystatinum**
Batch number / Weight: **24A11-B01-237253 / 5 G**
Analysed according to: **Ph.Eur.11.3**
Number of analysis / Inspection Code **24A11-B01 / INS-24-0776**
Reference Code / No.: **V00753 / 39201223**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------|--|---------|-------|-----------------|
| Appearance | Yellow or slightly brown powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| Identification E | Conform | Conform | | |
| Specific absorbance | $\geq 0,60$ | 0,863 | | |
| Composition | Conform | Conform | | |
| Nystatin A1 | $\geq 85,0$ | 86,05 | % m/m | |
| Any other compound | $\leq 4,0$ | 3,19 | % | |
| Loss on drying | $\leq 5,0$ | 1,31 | % | |
| Sulphated ash | $\leq 3,5$ | 1,53 | % | |
| Assay | ≥ 4400 | 6523 | IU/mg | |
| | ≥ 4400 (as is) | 6438 | IU/mg | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, HASCO

Release:
Ewelina Gadzinowska
Qualified Person

22-03-2024

Expiration: 31-12-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl