

DATE: 16.03.2023

CERTIFICATE OF ANALYSIS

PRODUCT: N Y S T A T I N
BATCH NUMBER: 08300323A
Serial number: 214/23
Manufacturing date: 03 23
Date of control: 03 23
Expiry date: 28.02.2026
Pharmacopeia: Ph. Eur.
Storage: Store in the original package. Protect from light.
Do not store above 25 °C.

Characters: A yellow or slightly brownish powder, hygroscopic, practically insoluble in water, freely soluble in dimethylformamide and in dimethylsulphoxide, slightly soluble in methanol, practically insoluble in ethanol 96 %.

Determination	Specification	Results
Identification - IR	comparable with that of the Nystatin CRS	Conforms
Identification - HPLC	conforms	Conforms
Absorbance (A305)	min. 0.60	0.83
Loss on drying	max. 5.0 %	2.2 %
Sulphated ash	max. 3.5 %	1.1 %
Assay		
Assay	min. 5000 IU/mg	6421 IU/mg
Assay on dried substance	min. 5000 IU/mg	6565 IU/mg
Residual solvents		
Acetone	max. 5000 mg/kg	299 mg/kg
Methanol	max. 3000 mg/kg	110 mg/kg
n-butanol	max. 1000 mg/kg	32 mg/kg
Other volatile impurities		
Mesityl oxide	max. 200 mg/kg	28 mg/kg
Tiglic aldehyde	max. 200 mg/kg	<8 mg/kg
Microbial contamination		
TAMC	< 2000 CFU/g	Conforms
TYMC	< 200 CFU/g	Conforms
bile-tolerant gram-negative bacteria (including Escherichia coli and Salmonella species)	must be absent in 1 g	Conforms
Pseudomonas aeruginosa	must be absent in 1 g	Conforms
Staphylococcus aureus	must be absent in 1 g	Conforms
Clostridium species	must be absent in 1 g	Conforms
Composition		
Nystatin A1	min. 85.0 %	87.7 %
Any other compound	max. 4.0 %	2.5 %
Nystatin A1 (USP)	min. 85.0 %	87.3 %
Any other compound (USP)	max. 4.0 %	2.5 %

COMPLIES WITH SPECIFICATION

Stamp:

VUAB Pharma a.s.
Vltavská 53, 252 63 Roztoky
Quality Assurance

Signature, date: **Tomáš Prejza** 16.03.2023