

VUAB Pharma a.s.

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Czech Republic

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FOR EXAMPLE

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DATE: 11.3.2019

CERTIFICATE OF ANALYSIS

PRODUCT:	NYSTATIN
BATCH NUMBER:	09100219
Serial number:	150/19
Manufacturing date:	02 19
Date of control:	03 19
Expiry date:	28. 2. 2022
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 dimethylsulfoxide, slightly soluble in methanol, practically insoluble in alcohol.

Determination

Specification

Results

1.Loss on drying:	NMT 5.0 %	3.1 %
2.Identification (A):	A ₂₉₁ /A ₃₀₅ = 0.61 - 0.73	0.66
	A ₃₁₉ /A ₃₀₅ = 0.83 - 0.96	0.93
	A ₂₃₀ /A ₂₈₀ = 0.83 - 1.25	1.06
3.Identification (C):	complies with the test	conforms
4.Identification (D):	complies with the test	conforms
5.Sulphated ash:	NMT 3.5 %	1.6 %
6.Microbial assay:	NLT 4 400 I.U./mg on dried substance	6 622 I.U./mg on dried substance (6 417 I.U./mg on substance as is)
7.Absorbance (A ₃₀₅):	NLT 0.60	0.78
8.Microbial contamination:		
TAMC:	NMT 10 ³ CFU/g	conforms
TYMC:	NMT 10 ² CFU/g	conforms
•bile-tolerant gram-negative bacteria (including Escherichia coli and Salmonella species)	must be absent	absent
•Pseudomonas aeruginosa	must be absent	absent
•Staphylococcus aureus	must be absent	absent
•Clostridia species:	must be absent	absent
9.Residual solvents (Gas chromatography):		
•Acetone	NMT 5 000 mg/kg	103 mg/kg
•Methanol	NMT 3 000 mg/kg	67 mg/kg
•n-butanol	NMT 1 000 mg/kg	LT 7 mg/kg
10.Mesityl oxide (Gas chromatography):	NMT 500 mg/kg	12 mg/kg
11.2-methyl-2-butenal (Gas chromatography):	NMT 500 mg/kg	LT 2 mg/kg
12.Composition HPLC:		
•Nystatin A1	Minimum 85.0 %	90.4 %
•Any other compound	Maximum 4.0 %	conforms

C O M P L I A B L E T O P h . E u r . 9 . 7

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

Signature: Kateřina Purchartová

