

VUAB Pharma a.s.
Vltavská 53,Roztoky,252 63,Czech Republic

Nystatin

EP

Packing	Number from - to	Pcs	Batch No.:	In one package			Total in packaging		
				Net w (kg)	BOU	Gross w (kg)	Net w (kg)	BOU	Gross w (kg)
Fibre Drum	1. - 2.	2	30101121A	15,58	100,00	20,08	31,16	200,00	40,16

Totally: **2 drums** **200,00 bou**
Net w: **31,16 kg**
Gross w: **40,16 kg**

Marks:
Nystatin EP
Batch no:
Mfg.date:
Exp.date:
Gross / Net:
1.-2.

VUAB Pharma a.s.
Vltavská 53, 252 63 Roztoky
Czech Republic



Dear business partner,
In accordance with the EU direction of GDP 2015/C 95/01 dated March 19th, 2015 we are obliged to attach a datalogger with every shipment.
Please follow strictly the respective instructions put together with datalogger in a drum no. 1.
Please send the respective record from datalogger electronically immediately after arrival of goods and opening the drum no.1.
Thank you.

CERTIFICATE OF ANALYSIS

PRODUCT:	NYSTATIN
BATCH NUMBER:	30101121A
Serial number:	457/21
Manufacturing date:	11 21
Date of control:	11 21
Expiry date:	31.10.2024
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 C, D, E		
Identification C	complies with the test	Conforms
Identification D	complies with the test	Conforms
Identification E	complies with the test	Conforms
Identification (A)		
A291/A305	0.61 - 0.73	0.65
A319/A305	0.83 - 0.96	0.93
A230/A280	0.83 - 1.25	1.07
A230/A279 (USP)	0.90 - 1.25	1.09
Absorbance (A305)	min. 0.60	0.79
Loss on drying	max. 5.0 %	2.2 %
Sulphated ash	max. 3.5 %	1.3 %
Assay		
Assay	min. 5000 IU/mg	6419 IU/mg
Assay on dried substance	min. 5000 IU/mg	6563 IU/mg
Residual solvents		
Acetone	max. 5000 mg/kg	52 mg/kg
Methanol	max. 3000 mg/kg	32 mg/kg
n-butanol	max. 1000 mg/kg	14 mg/kg
Other volatile impurities		
Mesityl oxide	max. 200 mg/kg	3 mg/kg
Tiglic aldehyde	max. 200 mg/kg	<1 mg/kg
Microbial contamination		
TAMC	max. 2000 CFU/g	50 CFU/g
TYMC	max. 200 CFU/g	<10 CFU/g
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 %	90.2 %
Any other compound	max. 4.0 %	2.1 %
Nystatin A1 (USP)	min. 85.0 %	89.8 %
Any other compound (USP)	max. 4.0 %	2.1 %

VUAB Pharma a.s.

Vltavská 53, 252 63 Roztoky

Czech Republic

Tel No: +420 220 910 055

DATE: 23.11.2021

COMPLIES WITH SPECIFICATION

Stamp:

Signature:

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

Jan Pich

