ANALYSIS CERTIFICATE

Lot/Analysis/Analysis Nº: 260182

Product:	NYSTATIN
Lot:	260182
Expiry date:	31/12/2028
Reference:	Cumple PhEur12.1
Synonyms:	
Formula:	C47H75NO17
Molecular weight:	926,1 g/mol

Assay	Result	Specification	
Identification	Conform (B,E)		
Organoleptic properties	Conform		
Absorbance	0,81	>= 0,60	=
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	2,8 %	<= 5,0 %	
Sulphated ashes	1,4 %	<= 3,5 %	=
Antimicrobial power	6425 UI/mg s.p.s	>= 5000 UI/mg s.p.s.	
Nystatin A1	92,3 %	>= 85,0 %	
Any other compound	2,9 %	<= 4,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: 1-Butanol	< 5000 ppm	<= 5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: Yellow or slightly brownish powder, hygroscopic. Practically insoluble in water, freely soluble in dimethylformamide and in dimethyl sulfoxide, slightly soluble in methanol, practically insoluble in alcohol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 19/02/2026

Judgement:
APPROVED

Responsible: B. Chia
Technical director: Montserrat Enrique
Manufacturer: F01035 VUAB PHARMA
Manufacturer batch: 01200126

Product	Name	Capacity	Batch
1162608	NISTATINA	10 g	260182-F-1
1162608	NISTATINA	10 g	260182-F-2

1162609	NISTATINA	25 g	260182-G-1
1162615	NISTATINA	1 kg	260182-P-2
1162615	NISTATINA	1 kg	260182-P-3
1200213	NISTATINA	100 g	260182-J-1
1200213	NISTATINA	100 g	260182-J-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.
Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer
(=) UE certificate

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