



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251497

Product:	NYSTATIN
Lot:	251497
Expiry date:	30/06/2028
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C ₄₇ H ₇₅ NO ₁₇
Molecular weight:	926,1 g/mol

Assay	Result	Specification	
Identification	Conform (B,E)		
Organoleptic properties	Conform		
Absorbance	0,81	$\geq 0,60$	=
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	3,3 %	$\leq 5,0 \%$	
Sulphated ashes	1,4 %	$\leq 3,5 \%$	=
Antimicrobial power	6722 UI/mg s.p.s.	≥ 5000 UI/mg s.p.s.	
Nystatin A1	91,8 %	$\geq 85,0 \%$	
Any other compound	3,2 %	$\leq 4,0 \%$	
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: 02/09/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01035 VUAB PHARMA

Manufacturer batch: 16700625

Product	Name	Capacity	Batch
1162608	NISTATINA	10 g	251497-F-1
1162609	NISTATINA	25 g	251497-G-1

1162615	NISTATINA	1 kg	251497-P-1
1200213	NISTATINA	100 g	251497-J-1

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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