



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240164

Product:	NYSTATIN
Lot:	240164
Expiry date:	31/12/2026
Reference:	Cumple PhEur11.3
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	0,85	>= 0,60	
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	2,5 %	<= 5,0 %	
Sulphated ashes	1,4 %	<= 3,5 %	
Antimicrobial power	6541 UI/mg s.p.s.	>= 5000 UI/mg s.p.s.	
Nystatin A1	93,3 %	>= 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: 06/02/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01035

Manufacturer batch: 00100124

Product	Name	Capacity	Batch
1162608	NISTATINA	10 g	240164-F-1
1162608	NISTATINA	10 g	240164-F-2

1162609	NISTATINA	25 g	240164-G-1
1162609	NISTATINA	25 g	240164-G-2
1162615	NISTATINA	1 kg	240164-P-1
1162615	NISTATINA	1 kg	240164-P-2
1200211	NISTATINA (INACTIVO)	5 g	240164-E-1
1200211	NISTATINA (INACTIVO)	5 g	240164-E-2
1200213	NISTATINA	100 g	240164-J-1
1200213	NISTATINA	100 g	240164-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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