



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230158

Product:	NYSTATIN
Lot:	230158
Expiry date:	30/09/2025
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C ₄₇ H ₇₅ NO ₁₇
Molecular weight:	926,1 g/mol

Assay	Result	Specification	
Nystatin A1	93,0 %	>= 85,0 %	
Any other compound	1,9 %	<= 4,0 %	
Organoleptic properties	Conform		
Absorbance	0,80	>= 0,60	=
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Identification	Conform (B,E)		
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Loss on drying	3,8 %	<= 5,0 %	
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Sulphated ashes	0,85 %	<= 3,5 %	=
Antimicrobial power	6349 UI/mg s.p.s	>= 5000 UI/mg s.p.s.	

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: 10/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00050 S.C. ANTIBIOTICE S.A.

Manufacturer batch: 4012127

Product	Name	Capacity	Batch
1162608	NISTATINA	10 g	230158-F-1
1162608	NISTATINA	10 g	230158-F-2
1162608	NISTATINA	10 g	230158-F-3
1162608	NISTATINA	10 g	230158-F-4

1162609	NISTATINA	25 g	230158-G-1
1162609	NISTATINA	25 g	230158-G-2
1162609	NISTATINA	25 g	230158-G-3
1162609	NISTATINA	25 g	230158-G-4
1162615	NISTATINA	1 kg	230158-P-1
1162615	NISTATINA	1 kg	230158-P-2
1162615	NISTATINA	1 kg	230158-P-3
1162615	NISTATINA	1 kg	230158-P-4
1200211	NISTATINA (INACTIVO)	5 g	230158-E-1
1200211	NISTATINA (INACTIVO)	5 g	230158-E-2
1200213	NISTATINA	100 g	230158-J-1
1200213	NISTATINA	100 g	230158-J-2
1200213	NISTATINA	100 g	230158-J-3
1200213	NISTATINA	100 g	230158-J-4

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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