



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 222813

Product:	NYSTATIN
Lot:	222813
Expiry date:	31/01/2025
Reference:	Cumple PhEur10.7
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	0,72	>= 0,60	=
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	2,8 %	<= 5,0 %	
STORE IN REFRIGERATOR (2-8°C)			
Sulphated ashes	3,0 %	<= 3,5 %	=
Antimicrobial power	6420 UI/mg	> 5000 UI/mg s.p.s.	
Nystatin A1	93 %	>= 85 %	
Any other compound	1,9 %	<= 4,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#

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: 13/05/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00050

Manufacturer batch: 4011834

Product	Name	Capacity	Batch
1162608	NISTATINA	10 g	222813-F-1
1162609	NISTATINA	25 g	222813-G-1
1162615	NISTATINA	1 kg	222813-P-1

1200211	NISTATINA (INACTIVO)	5 g	222813-E-1
1200213	NISTATINA	100 g	222813-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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