



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 223798**

Product:	NYSTATIN
Lot:	223798
Expiry date:	31/03/2025
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C <sub>47</sub> H <sub>75</sub> NO <sub>17</sub>
Molecular weight:	926,1 g/mol

Assay	Result	Specification	
Identification	Conform (B,E)		
Organoleptic properties	Conform		
Absorbance	0,80	$\geq 0,60$	=
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	2,1 %	$\leq 5,0$ %	
Sulphated ashes	0,65 %	$\leq 3,5$ %	=
Antimicrobial power	6221 UI/mg s.p.s.	$\geq 5000$ UI/mg s.p.s.	
Nystatin A1	88 %	$\geq 85,0$ %	
Any other compound	$\leq 4,0$ %	$\leq 4,0$ %	
Residual solvent: Methanol	$< 3000$ ppm	$\leq 3000$ ppm	#
Residual solvent: acetone	$< 5000$ ppm	$\leq 5000$ 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: 25/07/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00050

Manufacturer batch: 4011931

Product	Name	Capacity	Batch
1162608	NISTATINA	10 g	223798-F-1
1162609	NISTATINA	25 g	223798-G-1
1162609	NISTATINA	25 g	223798-G-2
1162615	NISTATINA	1 kg	223798-P-1

1162615	NISTATINA	1 kg	223798-P-2
1200211	NISTATINA (INACTIVO)	5 g	223798-E-1
1200211	NISTATINA (INACTIVO)	5 g	223798-E-2
1200213	NISTATINA	100 g	223798-J-1
1200213	NISTATINA	100 g	223798-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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