

## Nystatin

<b>CODE ARTICLE:</b> 9833	<b>BATCH:</b> 0127647	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 13/05/2024	<b>TEST:</b> QC-00264270	
<b>EXPIRY DATE:</b> 28/02/2027	<b>FABRICATION DATE:</b> 01/02/2024	<b>MR:</b> 926,10
<b>CAS:</b> [1400-61-9]	<b>FORMULA:</b> C47H75NO17	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			POWDER	PH.EUR.*
COLOUR	PASS -			YELLOW	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE	FREELY SOLUBLE IN DIMETHYLFORMAMIDE				PH.EUR.
SOLUBLE	FREELY SOLUBLE IN DMSO				PH.EUR.
SOLUBLE	SLIGHTLY SOLUBLE IN METHANOL				PH.EUR.
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.
INSOLUBLE	PRACTICALLY INSOLUBLE IN ETHANOL				PH.EUR.
<b>IDENTIFICATION</b>					
<b>IDENTIFICACION A (UV)</b>					
ABSORBANCE 230-280nm	1,06	nm	0,83	1,25	PH.EUR.
ABSORBANCE 291-305nm	0,65	nm	0,61	0,73	PH.EUR.
ABSORBANCE 319-305nm	0,91	nm	0,83	0,96	PH.EUR.
IDENTIFICATION B (IR)	PASS				PH.EUR.*
IDENTIFICATION C	PASS				PH.EUR.
IDENTIFICATION D	PASS				PH.EUR.
IDENTIFICACION E (HPLC)	PASS				PH.EUR.*
<b>COMPOSITION</b>					
NYSTATIN A1	96,0	%	85,0		PH.EUR.*
OTHER COMPONENTS	0,9	%		4,0	PH.EUR.*
ABSORBANCE 305nm	0,8134	-	0,6	1	PH.EUR.
LOSS ON DRYING	0,2	%	0,0	5	PH.EUR.*
SULPHATED ASHES	0,73	%	0,0	3,5	PH.EUR.
CONTENIDO IU/mg	6527,7	ui/mg	5.000	-	PH.EUR.*
PH	7,91	-	6	8	Manufacture's Standard
<b>RESIDUAL SOLVENTS</b>					
METHANOL	0,03	%		0,3	Manufacture's Standard
ACETONE	0,27	%		0,5	Manufacture's Standard
PARTICLE SIZE 90%	29,34	MICRONS	-	45	Manufacture's Standard
<b>MICROBIOLOGICAL CONTROL</b>					
TOTAL AEROBICS	30	UFC/G		1000	Manufacture's Standard
MOLDS AND YEASTS	<1	UFC/G		100	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 43309 S. C. A. S.A. (Rumanía) Manufacturer Batch: 401 2735 Manufacturer original CoA available under request

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TEST	RESULTS	Units	MIN	MAX	METHOD
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	PASS				
Risk Assessment Evaluation for Nitrosamines	PASS				



**Silvia Sancho-Tello Ripoll**  
Technical Director.

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