

Nystatin

CODE ARTICLE: 1500	BATCH: 0135177	Active pharmaceutical ingredient
TEST DATE: 24/03/2025	TEST: QC-00273944	
EXPIRY DATE: 30/01/2028	FABRICATION DATE: 01/01/2025	MR: 926,10
CAS: [1400-61-9]	FORMULA: C47H75NO17	
SYNONYMS / BOTANICAL NAME: Fungicidina		
STORAGE: 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.*
<u>SOLUBILITY</u>					
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 (96)				PH.EUR.
<u>IDENTIFICATION</u>					
<u>IDENTIFICATION A (UV)</u>					
ABSORBANCE 230-280nm	1,07 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.
IDENTIFICATION E (HPLC)	PASS				PH.EUR.*
<u>COMPOSITION</u>					
NYSTATIN A1	97,5 %		85,0		PH.EUR.*
OTHER COMPONENTS	0,6 %			4,0	PH.EUR.*
ABSORBANCE 305nm	0,8193 -		0,6	1	PH.EUR.
LOSS ON DRYING	0,1 %		0,0	5	PH.EUR.*
SULPHATED ASHES	0,91 %		0,0	3,5	PH.EUR.
CONTENT IU/mg	6480 ui/mg		5.000	-	PH.EUR.*
PH	7,36 -		6	8	Manufacture's Standard
<u>RESIDUAL SOLVENTS</u>					
METHANOL	0,01 %			0,3	Manufacture's Standard
ACETONE	0,25 %			0,5	Manufacture's Standard
PARTICLE SIZE 90%	29,51 MICRONS		-	45	Manufacture's Standard
<u>MICROBIOLOGICAL CONTROL</u>					
TOTAL AEROBICS	45 UFC/G			1000	Manufacture's Standard
MOLDS AND YEASTS	<1 UFC/G			100	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	PASS				

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 3143 Manufacturer original CoA available under request

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Risk Assessment Evaluation for Nitrosamines	PASS				



Silvia Sancho-Tello Ripoll
Technical Director.

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