

Nystatin

CODE ARTICLE: 77029	BATCH: 0129995	Active pharmaceutical ingredient
TEST DATE: 29/08/2024	TEST: QC-00267259	
EXPIRY DATE: 30/03/2027	FABRICATION DATE: 01/03/2024	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				PH.EUR.
<u>IDENTIFICATION</u>					
<u>IDENTIFICACION 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.
IDENTIFICACION E (HPLC)	PASS				PH.EUR.*
<u>COMPOSITION</u>					
NYSTATIN A1	96,1 %		85,0		PH.EUR.*
OTHER COMPONENTS	1,2 %			4,0	PH.EUR.*
ABSORBANCE 305nm	0,7688 -		0,6	1	PH.EUR.
LOSS ON DRYING	0,2 %		0,0	5	PH.EUR.*
SULPHATED ASHES	0,92 %		0,0	3,5	PH.EUR.
CONTENIDO IU/mg	6179 ui/mg		5.000	-	PH.EUR.*
PH	7,72 -		6	8	Manufacture's Standard
<u>RESIDUAL SOLVENTS</u>					
METHANOL	0,02 %			0,3	Manufacture's Standard
ACETONE	0,22 %			0,5	Manufacture's Standard
PARTICLE SIZE 90%	31,54 MICRONS		-	45	Manufacture's Standard
<u>MICROBIOLOGICAL CONTROL</u>					
TOTAL AEROBICS	25 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 2797 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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