

Nystatin

CODE ARTICLE: 78269	BATCH: 0117720	Active pharmaceutical ingredient
TEST DATE: 20/03/2023	TEST: QC-00251479	
EXPIRY DATE: 30/11/2025	FABRICATION DATE: 30/11/2022	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	POWDER				PH.EUR.*
COLOUR	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	1,06 nm		0,83	1,25	PH.EUR.
ABSORBANCE 291-305nm	0,65 nm		0,61	0,73	PH.EUR.
ABSORBANCE 319-305nm	0,92 nm		0,83	0,96	PH.EUR.
IDENTIFICACION B (IR)	CONFORM				PH.EUR.*
IDENTIFICACION C	CONFORM				PH.EUR.
IDENTIFICACION D	CONFORM				PH.EUR.
IDENTIFICACION E (HPLC)	CONFORM				PH.EUR.*
<u>COMPOSITION</u>					
NYSTATIN A1	93,5 %		85,0		PH.EUR.*
OTHER COMPONENTS	<4,0 %			4,0	PH.EUR.*
ABSORBANCE 305nm	0,74 -		0,6	1	PH.EUR.*
LOSS ON DRYING	0,2 %		0,0	5	PH.EUR.*
SULPHATED ASHES	0,5 %		0,0	3,5	PH.EUR.*
CONTENIDO IU/mg	6353 ui/mg		5.000	-	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	0,03 %			0,3	Manufacture's Standard
ACETONE	0,31 %			0,5	Manufacture's Standard
PARTICLE SIZE <45 MICRON	32 nm		0,0	100	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
CORRECT BATCH	YES				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 2238 Manufacturer original CoA available under request

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



Silvia Sancho-Tello Ripoll
Technical Director.

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