

Nystatin

CODE ARTICLE: 9833	BATCH: 0126322	Active pharmaceutical ingredient
TEST DATE: 20/03/2024	TEST: QC-00262561	
EXPIRY DATE: 31/10/2026	FABRICATION DATE: 01/10/2023	MR: 926,10
CAS: [1400-61-9]	FORMULA: C47H75NO17	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POLVO	PH.EUR.*
COLOUR	CONFORM	-		AMARILLO	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>IDENTIFICACION A (UV)</u>					
ABSORBANCE 230-280nm	1,03	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.
IDENTIFICATION B (IR)	CONFORM				PH.EUR.*
IDENTIFICATION C	CONFORM				PH.EUR.
IDENTIFICATION D	CONFORM				PH.EUR.
IDENTIFICACION E (HPLC)	CONFORM				PH.EUR.*
<u>COMPOSITION</u>					
NYSTATIN A1	98,3	%	85,0		PH.EUR.*
OTHER COMPONENTS	0,5	%		4,0	PH.EUR.*
ABSORBANCE 305nm	0,7229	-	0,6	1	PH.EUR.
LOSS ON DRYING	3,1	%	0,0	5	PH.EUR.*
SULPHATED ASHES	1	%	0,0	3,5	PH.EUR.
CONTENIDO IU/mg	6591	ui/mg	5.000	-	PH.EUR.*
PH	7,81	-	6	8	Manufacture's Standard
<u>RESIDUAL SOLVENTS</u>					
METHANOL	0,01	%		0,3	Manufacture's Standard
ACETONE	0,24	%		0,5	Manufacture's Standard
PARTICLE SIZE 90%	34,82	MICRONS	-	45	Manufacture's Standard
<u>MICROBIOLOGICAL CONTROL</u>					
TOTAL AEROBICS	40	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 2597 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	CONFORM				
Risk Assessment Evaluation for Nitrosamines	CONFORM				



Silvia Sancho-Tello Ripoll
Technical Director.

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