

Centrient Pharmaceuticals Netherlands B.V.

Alexander Fleminglaan 1, 2613 AX Delft, The Netherlands
P.O. Box 425, 2600 AK Delft, The Netherlands
Telephone 0031 (0) 15 2799111

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Certificate of Analysis

NYSTATIN

NYSTATIN MICRONIZED

Manufacturing date: Dec 2019

Batch/lot: C131395

Batch/lot size: 97.20 KG

Expiration Date: Nov 2022

Release Date: 26-May-2020

Tests	Specifications	Units	Results
U.V. Spectroscopy A230 nm / A279 nm	0,90 to 1,25		1,05
U.V. Spectroscopy A291 nm / A305 nm	0,61 to 0,73		0,66
U.V. Spectroscopy A319 nm / A305 nm	0,83 to 0,96		0,92
U.V. Spectroscopy A230 nm / A280 nm	0,83 to 1,25		1,03
Identification C & D	Complies with EP		Complies
Potency (USP) ¹	> = 5000 •	u/mg	6230 (STD Potency)
Loss on drying	< = 5,0	% w/w	4,0
Sulphated ash	< = 3,5	% w/w	Complies if tested*
Absorbance at 305 nm	> = 0,60		0,81
pH (c= 3%)	6,0 to 8,0		7,6
Crystallinity	It reveals birefringence		Responding
Suspendibility-USP	Complies to specification		Complies
Microbial count: Total aerobic bacteria	< = 1000	CFU/g	< 5
Microbial count: Yeast and moulds	< = 100	CFU/g	< 5
Composition HPLC: Nystatin A1	> = 85,0	% area	92,5
Composition HPLC: Any other compound	< = 4,0	% area	1,1
Residual solvents: Acetone	< = 0,5	% w/w	Complies if tested*
Residual solvents: Methylisobutylketone	< = 0,05	% w/w	Complies if tested*

Pharmacopoeia quality: Complies with the current editions of USP, EP & BP

Grade: ROW (Rest of World)

Characters: Yellow to light tan powder. Is hygroscopic and is affected by long exposure to light, heat and air. Freely soluble in dimethylformamide and in dimethyl sulfoxide; very slightly soluble in methanol; practically insoluble or insoluble in water, in alcohol, in n-propyl alcohol, in n-butyl alcohol, in chloroform and in ether.

Product suitable for use in the extemporaneous preparation of oral suspension.

This batch is not released as per the approved US and EU registration files of Centrient Pharmaceuticals Netherlands B.V.

* Test is performed at regular intervals

Manufactured by:
Capua BioServices S.p.A
Sede Legale- Amministrativa e Stabilimento:
Strada Statale Appia, 46-48
81043 Capua (CE) -Italy

Our sales order#: 72268
Customer order#: 4500195252-102825

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Ship-to LABORATORIOS CHILE, S.A. , CAMINO MELEPILLAN N° 9978 , , CERRILLOS SANTIAGO
, CL

*Tested against current USP standard (on as is basis)

Date of Issue: , July 01, 2020

COA approved with Digital Signature by Vincenzo
Marotta, Quality Manager & Qualified Person,
09:10:16, 01.07.2020

The material covered by this delivery is produced in accordance with the approved manufacturing specifications currently in force for this product grade. Capua BioServices certifies that the material supplied conforms to the performance typical for this grade and product description, and has been monitored in accordance with the internal quality control routines employed in our company, however, the buyer must check the suitability of this grade for the actual application. This certificate does not release the recipient from his obligation to carry out his usual incoming goods checks.