

QUALITY CERTIFICATE

Product name: NYSTATIN
Quality: Ph.Eur.11.0.
Package: 50 g
Formula: C₄₇H₇₅NO₁₇
Rel. mol. weight: 962,10
Lot No.: GF6059514
Manufacturing date: 07.2023.
Expiry date: 30.06.2026. (DMY)
Anal. No.: 15842H59514

	REQUIRED	MEASURED
Appearance:	yellow or slightly brownish, hygroscopic powder	yellow or slightly brownish, hygroscopic powder
Identity (IR)	identical	identical
Identification test 'C'	identical	identical
Identification test 'D'	identical	identical
Absorbance (A305 nm)	min.0,6	0,79
Nystatin A1 (HPLC)	min.85,0 %	89,3 %
Any other compound (HPLC)	max.4,0 %	<4,0 %
Loss on drying	max.5,0 %	3,6 %
Sulphated ash	max.3,5 %	1,65 %
Assay (microbiol.)	min.4400 IU/mg	6432 IU/mg
Residual solvents (Methanol)	max.3000 ppm	51 ppm
Residual solvents, (acetone)	max.5000 ppm	345 ppm
Residual solvents, (n-butanol)	max.1000 ppm	34 ppm

The Product complies with the requirements of Ph.Eur.11.0.

Kiállítva: Halásztelek, 2023.09.05.


Nagy Balázs

minőségbiztosítási vezető

Molar Chemicals Kft.
2314 Halásztelek, Árpád utca 1.
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Cégj.sz.: 13-09-1. 67293