

# Specification

## Technical Data Sheet

<b>Product Name</b>	Nystatin dihydrate
<b>Product No</b>	19268873
<b>CAS Number</b>	1400-61-9
<b>Storage Temperature</b>	2 to 8 °C
<b>Molecular Weight</b>	962.10
	<b>Specification</b>
<b>Appearance</b>	Yellow or brown yellow powder
<b>Conclusion</b>	Conforms to Ph.Eur. 9.7
<b>Loss on Drying</b>	≤5.0%
<b>pH</b>	6.0-8.0 (3% aqueous solution)
<b>Pseudomonas aeruginosa</b>	Absent
<b>A230/A280</b>	0.83-1.25
<b>A291/A305</b>	0.61-0.73

## Specification

<b>A319/A305</b>	0.83-0.96
<b>Absorbance A305</b>	$\geq 0.6$
<b>Assay (HPLC)</b>	Nystatin A1 $\geq 85\%$
<b>bile-tolerant gram-negative bacteria (E.coli + Salmonella sp.)</b>	Absent
<b>Clostridia species</b>	Absent
<b>Identification (U.V.) Test A</b>	identical with reference
<b>Residual Solvent (Acetone)</b>	$\leq 5000\text{ppm}$
<b>Residual Solvents (1-butanol)</b>	$\leq 1000\text{ppm}$
<b>Sulfated ash</b>	$\leq 3.5\%$
<b>I.D. Test D</b>	Conforms (UV)
<b>Mesityloxide</b>	$\leq 500\text{ppm}$
<b>Microbial Assay</b>	(As is)
<b>Microbial assay (dried)</b>	$\leq 4400 \text{ I.U./mg}$
<b>Residual Solvent Methanol</b>	$\leq 3000\text{ppm}$
<b>Staphylococcus Aureus</b>	Absent
<b>TAMC</b>	$\leq 1000 \text{ cfu/g}$
<b>TYMC</b>	$\leq 100 \text{ cfu/g}$