Hangzhou Hyper Chemicals Limited
RM 803, Tower 4, LOFT49 Pioneer Zone, 88 Jiru Road, Gongshu District, Hangzhou, 310015, China
Tel:+86 571 87702781 Fax:+86 571 86056590 Email: info@hyper-chem.com

CERTIFICATE OF ANALYSIS

Product Name:	Nystatin		
Batch No.	HS20220907	Quantity	188.6kgs
Manufacturing Date	September 10, 2022	Expiry Date TO	September 9, 2025
Report Date	September 24, 2022	Quality Specification	USP42/EP9.0/BP2018
Analytical results			
Items	Specifications		Results
Appearance	Yellow or slightly brownish powder, hyeroscopic.		Conform
Identification	IR		Conform
	HPLC		Conform
Solubility	Freely soluble in dim ethylformamide and in Domethylsulfoxide; slightly to sparingly soluble in methanol, in n-propyl alcohol and in n-butyl alcohol; practically insoluble in water and in alcohol; insoluble in chloroform and in ether.		Conform
Absorbance	0.9~1.25(230nm/279m)		1.04
	0.61 ~0.73(291nm/305nm)		0.67
	0.83~0.96(319nm/305nm)		0.92
	0.83~ 1.25(230nm/280nm)		1.02
	≥0.60(305nm)		0.82
Loss on drying	≤5.0%		4.00%
Heavy metals	≤20ppm		< 20ppm
Sulphated ash	≤3.5%		0.49%
pH	6.0~8.0		7.7
Suspensions	≥90%		97.5%
Nystatin component	Nystatin A1: ≥85%		90.70%
	Any other individual component: ≤4.0%		1.51%
Residual Solvents	Methanol: ≤0.3%		0.21%
	Acetone: ≤0.5%		0.30%
Assay	Not less than 5000 Nystatin Units Per mg		6091 IU/mg
Particle size	90% ≤40μm		22.1μm
Packaging and storage	Preserve in tight, light-resistant containers.		
Conclusion	The specification conforms with USP42/EP9.0/BP2018 Standard.		

Inspector: Carlifor Wu Verifier: Jack He