DSM Sinochem Pharmaceuticals

Nystatin Powder

Therapeutical category:

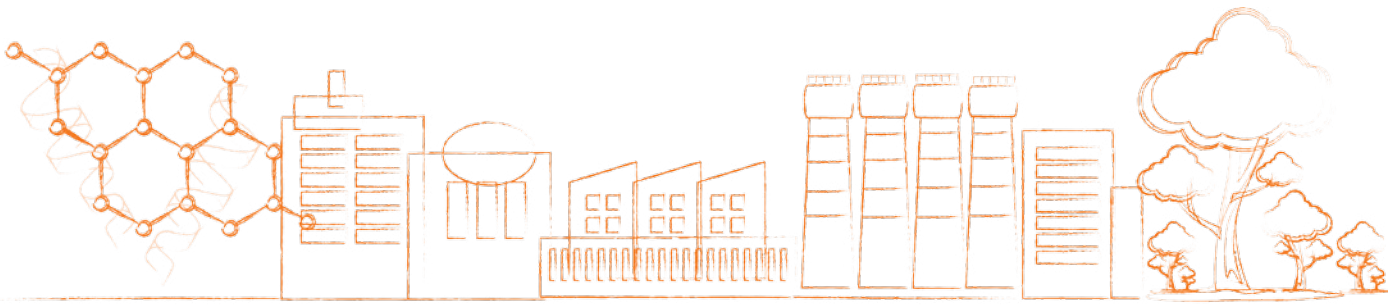
Polyene antibiotic with antifungal activity for oral use and topical use

Characteristics:

A crystalline powder

Applications:

The product is suitable for the manufacture of different dosage forms, such as topical emulsions, ointments, tablets and vaginal tablets, after the addition of the appropriate excipients.



Key parameters: Nystatin Powder

Pharmacopeia quality	USP, EP	
Regulatory information	USA: FDA EU: EDQM Italy: AIFA	Canada: HC Australia: TGA Japan: PMDA
Appearance	A yellow or slightly brownish powder	
Potency	≥ 5000 IU/mg (EP) ≥ 5500 U/mg (USP)	
Loss on drying	≤ 5.0%	
Composition (by HPLC)	Nystatin A1: ≥ 85% Any other compound: ≤ 4.0%	
Residual solvents	Acetone: ≤ 0.5% (EP) Acetone: ≤0.20% (USP) Methylisobutylketone: ≤ 0.05%	
Shelf-life	3 years in the original packaging under storage conditions	
Batch size	Approximately 200 kg	
Storage conditions	Below 25°C, protected from light and moisture	
Packaging	Primary packaging: polyethylene bag	
	Secondary packaging: thermo-sealed multilayer aluminum polyethylene bag	
	Outer packaging: corrugated box	
	Fixed quantity of the product (16.84 kg) equivalent to the desired total potency is packed in each box (103 BoIU for EP or 105 BoU for the USP grade product)	

Contact and information

For more information, please visit www.dsm-sinochem.com or e-mail: info@dsm-sinochem.com or contact us at one of the addresses below:

Singapore (HQ)
sales@dsm-sinochem.com

Europe/North America
Delft, The Netherlands
sales.ea@dsm-sinochem.com

Asia Pacific / Middle East / Africa
Gurgaon, India
sales.amea@dsm-sinochem.com

China
Beijing, P.R. China
sales.china@dsm-sinochem.com

Mexico & Latin America
Ramos Arizpe, Mexico
sales.mla@dsm-sinochem.com

V07.09.2017