DSM Sinochem Pharmaceuticals

Nystatin Powder

Therapeutical category:

Polyene antibiotic with antifungal activity for oral use and topical use

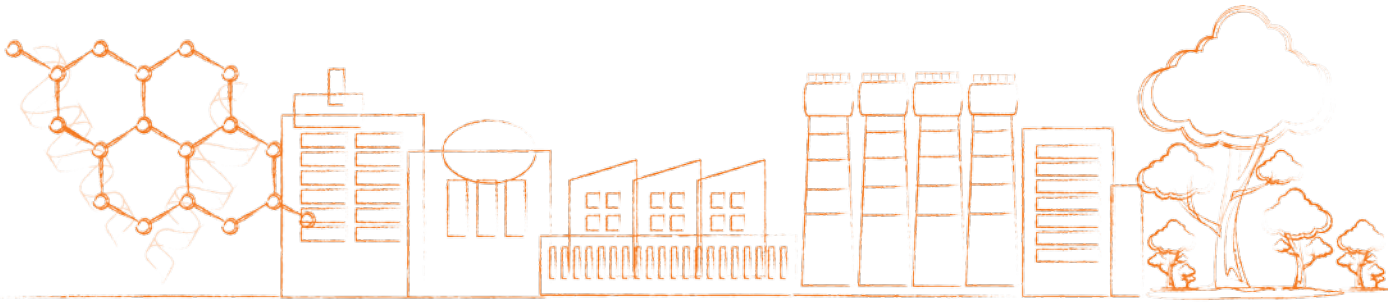
Characteristics:

A crystalline powder

Applications:

The product is suitable among others for the manufacture of creams, ointments, tablets and vaginal tablets after the addition of the appropriate excipients

All our manufacturing sites use the best available technology and operate dedicated waste water treatment plants, 24/7 throughout the year. Effluents are regularly sampled and checked for antimicrobial activity.



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: ≤0.2% (USP) Methylisobutylketone: ≤ 0.05%	
Shelf-life	Minimum 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 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 (99 BoIU for EP or 114 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:

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