

# Nystatin Powder

## Therapeutical category:

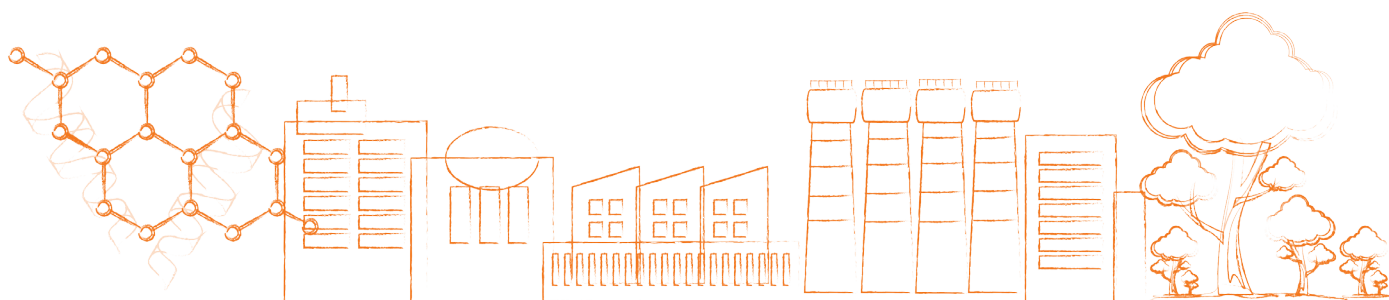
Polyene antibiotic with antifungal activity for oral use and topical use

## 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



## Key parameters: Nystatin Powder

<b>Pharmacopeia quality</b>	USP, EP	
<b>Regulatory information</b>	USA: FDA EU: EDQM Italy: AIFA	Canada: HC Australia: TGA Japan: PMDA
<b>Appearance</b>	A yellow or slightly brownish powder	
<b>Potency</b>	≥ 5000 IU/mg (EP) ≥ 5500 U/mg (USP)	
<b>Loss on drying</b>	≤ 5.0%	
<b>Composition (by HPLC)</b>	Nystatin A1: ≥ 85% Any other compound: ≤ 4.0%	
<b>Residual solvents</b>	Acetone: ≤ 0.5% (EP) Acetone: ≤ 0.2% (USP) Methylisobutylketone: ≤ 0.05%	
<b>Shelf-life</b>	3 years in the original packaging under storage conditions	
<b>Batch size</b>	Approximately 200 kg	
<b>Storage conditions</b>	Below 25°C, protected from light and moisture	
<b>Packaging</b>	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 BoU for EP or 114 BoU for the USP grade product)	

## Contact and information

For more information, please visit [www.dsm-sinochem.com](http://www.dsm-sinochem.com) or e-mail: [info@dsm-sinochem.com](mailto:info@dsm-sinochem.com) or contact us at one of the addresses below:

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