CENTRIENT™ Pharmaceuticals

Nystatin Micronized

Therapeutical category:

Polyene antibiotic with antifungal activity for oral use

Characteristics:

A microfine crystalline powder

Applications:

The product is suitable for the manufacture of oral suspensions and powders for extemporaneous oral suspensions.

Key parameters: Nystatin Micronized

Pharmacopeia quality	USP, EP	
Regulatory information	USA: FDA EU: EDQM Italy: AIFA	Canada: HPB 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 (12.15 kg) equivalent to the desired total potency is packed in each box (74 BoIU for EP or 76 BoU for the USP grade product)	

Contact and information

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

Rottterdam (HQ)
sales@centrient.com

Europe/North America
Delft, The Netherlands
sales.ea@centrient.com

Asia Pacific / Middle East / Africa
Gurgaon, India
sales.amea@centrient.com

China
Beijing, P.R. China
sales.china@centrient.com

Mexico & Latin America
Ramos Arizpe, Mexico
sales.mla@centrient.com