METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

1337-TDS-ENG-2024

NISTATINA (EUR. PH.)		
DESCRIPTION DCI: nystatin	DESCRIPTION DOE: NISTATINA	
CAS Nº: 1400-61-9	EC Nº: 215-749-0	AEMPS CODE: 2027A
MOL. WEIGHT: 926,23	MOL. FORMULA: C47H75NO17	ARTICLE CODE: 1337

ATTRIBUTES	SHOULD BE
Appearance	Yellow or slightly brownish powder, hygroscopic
Solubility	Practically insoluble in water, freely soluble in dimethylformamide and in dimethyl sulfoxide, slightly soluble in methanol, practically insoluble in ethanol (96 %)
Identification B	Complies
Identification E	Complies
Absorbance	
350 nm	=> 0,60
Composition	
Nystatin A1	=> 85,0 %
Cualquier otro compuesto	=< 4,0 %
Loss on drying	=< 5,0 %
Sulfated ash	=< 3,5 %
Assay	=> 5000 IU/mg

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

Nystatin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.