METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

009877-TDS-ENG-2025

SIROLIMUS		
DESCRIPTION DCI: SIROLIMUS	DESCRIPTION DOE: SIROLIMUS	
CAS Nº: 53123-88-9	EC Nº: 610-965-5	AEMPS CODE: 1269A
MOL. WEIGHT: 914,19	MOL. FORMULA: C51H79NO13	ARTICLE CODE: 009877

ATTRIBUTES	SHOULD BE
Appearance	White crystalline powder
Identification (1)	Complies
Identification (2)	Complies
Related substances	
Tautomer (RT = 1.1)	=< 3.0 %
Individual impurities	=< 1.0 %
Total impurities	=< 3.0 %
Water	=< 1.0 %
Residue on ignition	=< 0.5 %
Assay	=> 94.0 %
Residual solvents [In-house]	
Acetone	=< 4000 ppm
Diethyleter	=< 4000 ppm
Ethyl acetate	=< 4000 ppm
Ethanol	=< 2000 ppm
Isopropyl ether	=< 2000 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence/1g
S. Aureus	Absence/1g
C. Albicans	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a well-ventilated area away from direct sunlight.

REMARKS

Sirolimus is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

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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.