METAPHARMACEUTICAL IND SL
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SIROLIMUS

PRODUCT CODE: 009877	CAS Nº: 53123-88-9	ANALYSIS Nº: 095/25	
MANUFACTURER BATCH:	HNSN2406502	CERTIFICATE ID:	46.037
SUPPLIER BATCH:	----	MANUFACTURING DATE:	15/06/2024
METAPH BATCH:	0120425	EXPIRY DATE:	14/06/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White crystalline powder	White crystalline powder
Identification (1)	Complies	Complies
Identification (2)	Complies	Complies
Related substances		
Tautomer (RT = 1.1)	=< 3.0 %	0.4 %
Individual impurities	=< 1.0 %	< 1.0 % (#)
Total impurities	=< 3.0 %	1.4 %
Water	=< 1.0 %	0.3 %
Residue on ignition	=< 0.5 %	0.1 %
Assay	=> 94.0 %	99.9 %
Residual solvents [In-house]		
Acetone	=< 4000 ppm	< 50 ppm
Diethyleter	=< 4000 ppm	Not Detected (*)
Ethyl acetate	=< 4000 ppm	373 ppm
Ethanol	=< 2000 ppm	< 50 ppm
Isopropyl ether	=< 2000 ppm	No Detected (*)
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
S. Aureus	Absence/1g	Absence/1g
C. Albicans	Absence/1g	Absence/1g
P. Aeruginosa	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

COMPLIES WITH

Manufacturer Specifications

REMARKS

(#) Impurities detailed underneath:
RT (5.60 min) = 0.1 %
RT (7.36 min) = 0.9 %
RT (18.60 min) = 0.4 %

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

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.

Analysis date: 03/06/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000447
NORTH CHINA PHARMACEUTICAL HUASHENG Co., Ltd.
No.8 Yangzi Road,
Shijiazhuang Economic & Technical Development

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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.

STORAGE

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

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