

## SIROLIMUS

PRODUCT CODE: 009877	CAS Nº: 53123-88-9	ANALYSIS Nº: 082/23
MANUFACTURER BATCH: HNSN2207502	CERTIFICATE ID: 37.991	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 22/07/2022	
METAPH BATCH: 0030423	RETEST DATE: 21/07/2025	

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 %	0.77 %
Individual impurities	=< 1.0 %	< 1.0 % (#)
Total impurities	=< 3.0 %	0.51 %
Water	=< 1.0 %	0.12 %
Residue on ignition	=< 0.5 %	0.02 %
Assay	=> 94.0 %	99.5 %
Residual solvents [In-house]		(*)
Acetone	=< 4000 ppm	139 ppm
Diethyleter	=< 4000 ppm	< 50 ppm
Ethyl acetate	=< 4000 ppm	< 50 ppm
Ethanol	=< 2000 ppm	251 ppm
Isopropyl ether	=< 2000 ppm	< 50 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g

### COMPLIES WITH

Manufacturer Specifications

### REMARKS

(#) Individual impurities detailes underneath:

RT (7.840 min) = 0.44 %

RT (10.503 min) = 0.07 %

All data controlled by Metapharmaceutical Industrial SL.

Sirolimus is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

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.

(\*) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

Analysis date: 19/04/2023

Signature: Ferran Gonzalez de Rivera Rier

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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### STORAGE

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

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