

## SIROLIMUS

PRODUCT CODE: 009877	CAS Nº: 53123-88-9	ANALYSIS Nº: 098/24
MANUFACTURER BATCH: HNSN2402501	CERTIFICATE ID: 41.794	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 21/02/2024	
METAPH BATCH: 0100424	RETEST DATE: 20/02/2027	

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 %	0.2 %
Individual impurities	=< 1.0 %	< 1.0 % (#)
Total impurities	=< 3.0 %	0.3 %
Water	=< 1.0 %	0.3 %
Residue on ignition	=< 0.5 %	< 0.1 %
Assay	=> 94.0 %	100.8 %
Residual solvents [In-house]		
Acetone	=< 4000 ppm	< 50 ppm
Diethyleter	=< 4000 ppm	Not Detected (*)
Ethyl acetate	=< 4000 ppm	< 50 ppm
Ethanol	=< 2000 ppm	< 50 ppm
Isopropyl ether	=< 2000 ppm	Not Detected (*)
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 detailed underneath:

RT (9.73 min) = 0.05 %

RT (18.94 min) = 0.20%

RT (21.35 min) = 0.05 %

Sirolimus 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".

(\*) Data adapted from the certificate of analysis of the manufacturer.

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 pharmacopeias 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.

Analysis date: 30/04/2024  
 Signature: Cristina Borrell Olea (QA/QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000447  
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