

SIROLIMUS

PRODUCT CODE: 009877	CAS Nº: 53123-88-9	ANALYSIS Nº: 258/23
MANUFACTURER BATCH: HNSN2207502	CERTIFICATE ID: 39.848	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 22/07/2022	
METAPH BATCH: 0090123	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 %	0.9 %
Individual impurities	=< 1.0 %	0.2 %
Total impurities	=< 3.0 %	0.3 %
Water	=< 1.0 %	0.3 % (*)
Residue on ignition	=< 0.5 %	0.04 %
Assay	=> 94.0 %	98.9 % (*)
Residual solvents [In-house]		
Acetone	=< 4000 ppm	27 ppm
Diethyleter	=< 4000 ppm	Not Detected
Ethyl acetate	=< 4000 ppm	Not Detected
Ethanol	=< 2000 ppm	Not Detected
Isopropyl ether	=< 2000 ppm	Not Detected
Microbiological control		
TAMC	=< 1000 CFU/g	< 20 CFU/g
TYMC	=< 100 CFU/g	< 20 CFU/g
Escherichia coli	Absence/1g	Absence/1g

COMPLIES WITH

Manufacturer Specifications

REMARKS

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

(*) Data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 16/11/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000447
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