



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233835

Product:	SIROLIMUS
Lot:	233835
Expiry date:	30/04/2026
Reference:	Especificaciones de fabricante
Synonyms:	Rapamicina.
Formula:	C51H79NO13
Molecular weight:	914,17 g/mol

Assay	Result	Specification	
STORE IN REFRIGERATOR (2-8°C)			
Total impurities	< 0,04 %	<= 0,70 %	
Assay (HPLC)	101,0 %	98,0 - 102,0 %	
Individual impurities	< 0,04 %	<= 0,15 %	
Related substances (HPLC)	Conform		
Isomer C	3,4 %	<= 5,0 %	
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residue on ignition	0,10 %	<= 0,1 %	
Isomer A	0,35 %	<= 0,5 %	
Loss on drying	0,09 %	<= 0,5 %	
Residual solvent: Petroleum ether	< 100 ppm	<= 100 ppm	#
Elemental impurities	Conform	Test	#
Residual solvent: Methyl formate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Organoleptic properties	Conform		
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Identification	Conform	IR	
Residual solvent: Diethyl ether	< 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White to almost white or yellow powder. Fairly insoluble in water, soluble in ethanol.

Conservation: In tightly closed containers. Protect from light. FRIDGE (2-8°C)

Date of analysis: 21/12/2023

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1608A523010

Product	Name	Capacity	Batch
1114450	SIROLIMUS	10 g	233835-F-1
1114451	SIROLIMUS	1 g	233835-D-1
1114451	SIROLIMUS	1 g	233835-D-2
1114451	SIROLIMUS	1 g	233835-D-3

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer
(=) UE certificate

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