



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224845

Product:	SIROLIMUS
Lot:	224845
Expiry date:	28/02/2025
Reference:	Especificaciones ACOFARMA
Synonyms:	Rapamicina.
Formula:	C ₅₁ H ₇₉ NO ₁₃
Molecular weight:	914,17 g/mol

Assay	Result	Specification	
Elemental impurities	Conform	Test	#
Residual solvent: Methyl formate	< 5000 ppm	<= 5000 ppm	#
Loss on drying	0,2 %	<= 0,5 %	
Residual solvent: Petroleum ether	< 250 ppm	<= 250 ppm	#
Residue on ignition	0,00 %	<= 0,2 %	
Isomer A	0,13 %	<= 0,5 %	
Related substances (HPLC)	Conform		
Isomer C	3,3 %	<= 5,0 %	
Assay (HPLC)	100,2 %	98,0 - 102,0 %	
Individual impurities	< 0,04 %	<= 0,15 %	
STORE IN REFRIGERATOR (2-8°C)			
Total impurities	< 0,04 %	<= 0,70 %	
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Identification	Conform	IR	
Residual solvent: Diethyl ether	< 5000 ppm	<= 5000 ppm	#
Organoleptic properties	Conform		
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 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: 23/11/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1608522004

Product	Name	Capacity	Batch
1114451	SIROLIMUS	1 g	224845-D-1

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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