



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241102

Product:	SIROLIMUS
Lot:	241102
Expiry date:	28/02/2027
Reference:	Especificaciones de fabricante
Synonyms:	Rapamicina.
Formula:	C ₅₁ H ₇₉ NO ₁₃
Molecular weight:	914,17 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform		
Elemental impurities	Conform	Test	#
Loss on drying	0,20 %	<= 0,5 %	
Residue on ignition	0,00 %	<= 0,1 %	
Related substances (HPLC)	Conform		
Assay (HPLC)	100,3 %	98,0 - 102,0 %	
STORE IN REFRIGERATOR (2-8°C)			
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Diethyl ether	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Methyl formate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Petroleum ether	< 100 ppm	<= 100 ppm	#
Isomer A	0,24 %	<= 0,5 %	
Isomer C	3,0 %	<= 5,0 %	
Individual impurities	0,04 %	<= 0,15 %	
Total impurities	0,04 %	<= 0,70 %	

Organoleptic characteristics: White or off-white powder. Soluble in acetonitrile, acetone and chloroform, practically insoluble in water.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/06/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1608A524006

Product	Name	Capacity	Batch
1114450	SIROLIMUS	10 g	241102-F-1
1114450	SIROLIMUS	10 g	241102-F-2
1114450	SIROLIMUS	10 g	241102-F-3
1114451	SIROLIMUS	1 g	241102-D-1
1114451	SIROLIMUS	1 g	241102-D-2
1114451	SIROLIMUS	1 g	241102-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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