



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 230506**

Product:	SIROLIMUS
Lot:	230506
Expiry date:	30/09/2025
Reference:	Especificaciones de fabricante
Synonyms:	Rapamicina.
Formula:	C <sub>51</sub> H <sub>79</sub> NO <sub>13</sub>
Molecular weight:	914,17 g/mol

Assay	Result	Specification	
Residue on ignition	0,00 %	<= 0,1 %	
Isomer A	0,29 %	<= 0,5 %	
Loss on drying	0,1 %	<= 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	#
STORE IN REFRIGERATOR (2-8°C)			
Total impurities	< 0,04 %	<= 0,70 %	
Assay (HPLC)	100,2 %	98,0 - 102,0 %	
Individual impurities	< 0,04 %	<= 0,15 %	
Related substances (HPLC)	Conform		
Isomer C	3,5 %	<= 5,0 %	
Residual solvent: Acetonitrile	< 410 ppm	<= 410 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: 07/03/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1608A522025

Product	Name	Capacity	Batch
1114451	SIROLIMUS	1 g	230506-D-1
1114451	SIROLIMUS	1 g	230506-D-2
1114451	SIROLIMUS	1 g	230506-D-3
1114451	SIROLIMUS	1 g	230506-D-4

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

ACOFARMA DISTRIBUCIÓN, S.A.  
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)  
Tel./ 93-736.00.88  
[www.acofarma.com](http://www.acofarma.com)

Date of edition: 02/01/2025

