



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250207

Product:	TACROLIMUS
Lot:	250207
Expiry date:	30/11/2027
Reference:	Cumple PhEur11.6
Synonyms:	Tacrolimus monohidrato.
Formula:	C ₄₄ H ₆₉ NO ₁₂ ·H ₂ O
Molecular weight:	822,03 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform	PhEur	
Water	2,1 %	1,5 - 4,0 %	
Appearance of solution	Conform	Test PhEur	
Sulphated ashes	0,01 %	<= 0,1 %	
Assay	100,3 %	97,0 - 102,0 %	
Related substances (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 0,05 %	<= 0,5 %	
Unspecified Impurities	0,07 %	<= 0,15 %	
Total impurities	0,13 %	<= 1,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Isopropyl ether	< 600 ppm	<= 600 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Hexane	< 290 ppm	<= 290 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, soluble in ethanol (96 per cent), practically insoluble in heptane.

Conservation: Store in tightly closed containers. Protect from light and moisture. Store at controlled room temperature

Date of analysis: 05/02/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 0403A524331

Product	Name	Capacity	Batch
1179899	TACROLIMUS	0,25 g	250207-B-1
1179900	TACROLIMUS	0,5 g	250207-C-2
1179901	TACROLIMUS	1 g	250207-D-2
1179902	TACROLIMUS	5 g	250207-E-1
1370220	TACROLIMUS (FLB)	1 g	250207-D-1
1370249	TACROLIMUS (FLB)	0,5 g	250207-C-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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