



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 252099**

Product:	TACROLIMUS
Lot:	252099
Expiry date:	21/10/2027
Reference:	Cumple PhEur11.8
Synonyms:	Tacrolimus monohidrato.
Formula:	C <sub>44</sub> H <sub>69</sub> NO <sub>12</sub> ·H <sub>2</sub> O
Molecular weight:	822 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform	PhEur	
Water	2,0 %	1,5 - 4,0 %	
Appearance of solution	Conform	Test PhEur	
Sulphated ashes	0,07 %	<= 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	0,05 %	<= 0,15 %	
Total impurities	0,05 %	<= 1,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 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	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Isopropylbenzene	< 70 ppm	<= 70 ppm	#
Residual solvent: Benzene	< 2 ppm	<= 2 ppm	#
Nitrosamine impurities	Conform		#

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: 04/12/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01057 WUXI FORTUNE PHARMACEUTICAL CO., LTD.

Manufacturer batch: AJ241002C

Product	Name	Capacity	Batch
1179899	TACROLIMUS	0,25 g	252099-B-1
1179899	TACROLIMUS	0,25 g	252099-B-2
1179900	TACROLIMUS	0,5 g	252099-C-2
1179900	TACROLIMUS	0,5 g	252099-C-3
1179901	TACROLIMUS	1 g	252099-D-2
1179901	TACROLIMUS	1 g	252099-D-3
1179902	TACROLIMUS	5 g	252099-E-1
1179902	TACROLIMUS	5 g	252099-E-2
1370220	TACROLIMUS (FLB)	1 g	252099-D-1
1370249	TACROLIMUS (FLB)	0,5 g	252099-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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