



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242043

Product:	CYCLOSPORINE A
Lot:	242043
Expiry date:	30/05/2028
Reference:	Cumple PhEur11.5
Synonyms:	
Formula:	C ₆₂ H ₁₁₁ N ₁₁ O ₁₂
Molecular weight:	1202,63 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	-186	(-185) - (-193)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,62 %	<= 2,0 %	
Assay (HPLC)	98,7 %	97,0 - 102,0 %	
Sum of impurities B and E	0,25 %	<= 0,5 %	
Impurity G	0,10 %	<= 0,4 %	
Any impurity	0,21 %	<= 0,3 %	
Total impurities	0,87 %	<= 1,5 %	
Residual solvent: Ethyl acetate	< 2000 ppm	<= 2000 ppm	#
Residual solvent: acetone	< 4500 ppm	<= 4500 ppm	#
Nitrosamine impurities	Conform		#

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride

Conservation: In tightly closed containers. Protect form light and moisture.

Date of analysis: 11/11/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1213A424107

Product	Name	Capacity	Batch
1119023	CICLOSPORINA A Ph.Eur.	5 g	242043-E-2
1119023	CICLOSPORINA A Ph.Eur.	5 g	242043-E-4

1119027	CICLOSPORINA A Ph.Eur.	100 g	242043-J-1
1119027	CICLOSPORINA A Ph.Eur.	100 g	242043-J-2
1119029	CICLOSPORINA A Ph.Eur.	1 kg	242043-P-1
1119029	CICLOSPORINA A Ph.Eur.	1 kg	242043-P-2
1370212	CICLOSPORINA A Ph.Eur. (FLB)	5 g	242043-E-1
1370212	CICLOSPORINA A Ph.Eur. (FLB)	5 g	242043-E-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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