



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241582

Product:	CYCLOSPORINE A
Lot:	241582
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	-187	(-185) - (-193)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,39 %	<= 2,0 %	
Assay (HPLC)	98,9 %	97,0 - 102,0 %	
Sum of impurities B and E	0,27 %	<= 0,5 %	
Impurity G	0,11 %	<= 0,4 %	
Any impurity	0,14 %	<= 0,3 %	
Total impurities	0,82 %	<= 1,5 %	
Residual solvent: Ethyl acetate	< 2000 ppm	<= 2000 ppm	#
Residual solvent: acetone	< 4500 ppm	<= 4500 ppm	#

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 from light and moisture.

Date of analysis: 29/08/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1213A424110

Product	Name	Capacity	Batch
1119023	CICLOSPORINA A Ph.Eur.	5 g	241582-E-2
1119025	CICLOSPORINA A Ph.Eur.	25 g	241582-G-1
1119027	CICLOSPORINA A Ph.Eur.	100 g	241582-J-1

1119029

CICLOSPORINA A Ph.Eur.

1 kg

241582-P-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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