



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240789**

Product:	CYCLOSPORINE A
Lot:	240789
Expiry date:	30/01/2028
Reference:	Cumple PhEur11.4
Synonyms:	
Formule:	C62H111N11O12
Poids moléculaire:	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	- 189	(-185) - (-193)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,49 %	<= 2,0 %	
Assay (HPLC)	98,9 %	97,0 - 102,0 %	
Sum of impurities B and E	0,27 %	<= 0,5 %	
Impurity G	0,09 %	<= 0,4 %	
Any impurity	0,18 %	<= 0,3 %	
Total impurities	0,49 %	<= 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: 22/05/2024

Judgement:  
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1213A424035

Produit	Nom	Capacité	Lot
1119025	CICLOSPORINA A Ph.Eur.	25 g	240789-G-1
1119027	CICLOSPORINA A Ph.Eur.	100 g	240789-J-1
1119029	CICLOSPORINA A Ph.Eur.	1 kg	240789-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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