



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 251191**

Product:	CYCLOSPORINE A
Lot:	251191
Expiry date:	30/01/2029
Reference:	Cumple PhEur11.7
Synonyms:	
Formula:	C <sub>62</sub> H <sub>111</sub> N <sub>11</sub> O <sub>12</sub>
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	(-190)	(-185) - (-193)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,40 %	<= 2,0 %	
Assay (HPLC)	99,1 %	97,0 - 102,0 %	
Sum of impurities B and E	0,22 %	<= 0,5 %	
Impurity G	0,10 %	<= 0,4 %	
Any impurity	0,24 %	<= 0,3 %	
Total impurities	0,62 %	<= 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: 19/06/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1213A425056

Product	Name	Capacity	Batch
1119023	CICLOSPORINA A Ph.Eur.	5 g	251191-E-1
1119027	CICLOSPORINA A Ph.Eur.	100 g	251191-J-1

1119029	CICLOSPORINA A Ph.Eur.	1 kg	251191-P-1
1119029	CICLOSPORINA A Ph.Eur.	1 kg	251191-P-2
1370212	CICLOSPORINA A Ph.Eur. (FLB)	5 g	251191-E-2

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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Date of edition: 07/06/2026