



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 232171

Product:	CYCLOSPORINE A
Lot:	232171
Expiry date:	28/02/2027
Reference:	Cumple PhEur11.1
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	- 190	(-185) - (-193)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,54 %	<= 2,0 %	
Assay (HPLC)	98,3 %	97,0 - 102,0 %	
Sum of impurities B and E	0,27 %	<= 0,5 %	
Impurity G	0,11 %	<= 0,4 %	
Any impurity	0,22 %	<= 0,3 %	
Total impurities	0,69 %	<= 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 form light and moisture.

Date of analysis: 12/05/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1213A423062

Product	Name	Capacity	Batch
1119022	CICLOSPORINA A Ph.Eur. (INACTIVO)	0,5 g	232171-C-1
1119023	CICLOSPORINA A Ph.Eur.	5 g	232171-E-1
1119023	CICLOSPORINA A Ph.Eur.	5 g	232171-E-2

1119023	CICLOSPORINA A Ph.Eur.	5 g	232171-E-3
1119025	CICLOSPORINA A Ph.Eur.	25 g	232171-G-1
1119025	CICLOSPORINA A Ph.Eur.	25 g	232171-G-2
1119025	CICLOSPORINA A Ph.Eur.	25 g	232171-G-3
1119027	CICLOSPORINA A Ph.Eur.	100 g	232171-J-1
1119027	CICLOSPORINA A Ph.Eur.	100 g	232171-J-2
1119027	CICLOSPORINA A Ph.Eur.	100 g	232171-J-3
1119029	CICLOSPORINA A Ph.Eur.	1 kg	232171-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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