



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230316

Product:	CYCLOSPORINE A
Lot:	230316
Expiry date:	31/10/2026
Reference:	Cumple PhEur11.0
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	(-189)	(-185) - (-193)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,3 %	<= 2,0 %	
Assay (HPLC)	100,1 %	97,0 - 102,0 %	
Sum of impurities B and E	0,24 %	<= 0,5 %	
Impurity G	0,10 %	<= 0,4 %	
Any impurity	0,17 %	<= 0,3 %	
Total impurities	0,6 %	<= 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: 28/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1213A422164

Product	Name	Capacity	Batch
1119030	CICLOSPORINA A Ph.Eur.	5 kg	230316-Q-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

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

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