



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 251969**

Product:	Cyclophosphamide
Lot:	251969
Expiry date:	02/03/2027
Reference:	Cumple PhEur12.1
Synonyms:	
Formula:	C7H15Cl2N2O2P,H2O
Molecular weight:	279.1 g/mol

Assay	Result	Specification	
Identification	Conform (B)		
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
pH	5,6	4,0 - 6,0	
Elemental impurities	Conform	Test PhEur	#
Chlorides	< 330 ppm	<= 330 ppm	
Phosphates	< 100 ppm	<= 100 ppm	
Moisture	6,7 %	6,0 -7,0 %	
Assay	99,0 %	98,0 - 102,0 %	
Related substances (HPLC)	Conform		
Nitrosamine impurities	Conform	Test PhEur	#
Impurity A	0,06 %	<= 0,15 %	
Impurity C	0,09 %	<= 0,3 %	
Unspecified Impurities	ND	<= 0,05 %	
Total impurities	0,15 %	<= 0,5 %	
Impurity G	< 0,025 %	<= 0,025 %	#
Residual solvent: tert-butyl methyl ether	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Benzene	<= 2 ppm	<= 2 ppm	#
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Related substances (TLC)	Conform		
Impurity D	< 0,06 %	<= 0,06 %	
Impurity E	< 0,06 %	<= 0,06 %	
Impurity F	< 0,06 %	<= 0,06%	
Unspecified impurities (TLC)	< 0,06 %	<= 0,06 %	

Organoleptic characteristics: White or almost white, crystalline powder. Soluble in water, very soluble in methylene chloride, freely soluble in ethanol (96 per cent).

Conservation:

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Date of analysis: 23/01/2026

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01049 ANHUI POLY PHARM. CO., LTD.

Manufacturer batch: 3550800300

Product	Name	Capacity	Batch
1100083	CICLOFOSFAMIDA MONOHIDRATO	10 g	251969-F-1
1100083	CICLOFOSFAMIDA MONOHIDRATO	10 g	251969-F-2
1100084	CICLOFOSFAMIDA MONOHIDRATO	25 g	251969-G-1
1100084	CICLOFOSFAMIDA MONOHIDRATO	25 g	251969-G-2
1100085	CICLOFOSFAMIDA MONOHIDRATO	100 g	251969-J-1
1100085	CICLOFOSFAMIDA MONOHIDRATO	100 g	251969-J-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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