



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 251611**

Product:	CLINDAMYCIN HYDROCHLORIDE
Lot:	251611
Expiry date:	07/01/2028
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C <sub>18</sub> H <sub>33</sub> CIN <sub>2</sub> O <sub>5</sub> S·HCl
Molecular weight:	461,44 g/mol

Assay	Result	Specification	
Identification	Conform (A,D)	Test PhEur (A,D)	
Organoleptic properties	Conform	PhEur	
pH	4,6	3,0-5,0	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	(+143 )	(+135°)-(+150°)	
Moisture - K.F. (s/0,5g)	3,9 %	3,0-6,0%	
Sulphated ashes	0,02 %	<= 0,5%	
Assay (HPLC)	97,9 %	92,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity B	0,17 %	<=2,0 %	
Impurity C	0,63 %	<= 4,0 %	
Any other impurity	< 0,05 %	<= 0,5 %	
Total impurities	0,80 %	<= 6,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	< 600 ppm	<= 60 ppm	#

Organoleptic characteristics: White or almost white crystalline powder. Very soluble in water, slightly soluble in ethanol 96%.

Conservation: In tightly closed containers. Protect form light and moisture.

Date of analysis: 15/09/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00124 ZHEJIANG TIANAI PHARMACEUTICAL, Co. Ltd.

Manufacturer batch: K-250106B

Product	Name	Capacity	Batch
1119574	CLINDAMICINA CLORHIDRATO	5 g	251611-E-1

1119574	CLINDAMICINA CLORHIDRATO	5 g	251611-E-2
1119576	CLINDAMICINA CLORHIDRATO	25 g	251611-G-2
1119576	CLINDAMICINA CLORHIDRATO	25 g	251611-G-4
1119577	CLINDAMICINA CLORHIDRATO	100 g	251611-J-1
1119577	CLINDAMICINA CLORHIDRATO	100 g	251611-J-3
1119580	CLINDAMICINA CLORHIDRATO	1 kg	251611-P-1
1370038	CLINDAMICINA CLORHIDRATO (FLB)	1 kg	251611-P-2
1370039	CLINDAMICINA CLORHIDRATO (FLB)	100 g	251611-J-2
1370041	CLINDAMICINA CLORHIDRATO (FLB)	25 g	251611-G-1
1370041	CLINDAMICINA CLORHIDRATO (FLB)	25 g	251611-G-3
1370043	CLINDAMICINA CLORHIDRATO (FLB)	1 g	251611-D-1
1370043	CLINDAMICINA CLORHIDRATO (FLB)	1 g	251611-D-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

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

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