



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240613**

Product:	CLINDAMYCIN HYDROCHLORIDE
Lot:	240613
Expiry date:	05/01/2027
Reference:	Cumple PhEur11.3
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	4,5	3,0-5,0	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+ 141 °	(+135°)-(+150°)	
Moisture - K.F. (s/0,5g)	3,7 %	3,0-6,0%	
Sulphated ashes	0,00 %	<= 0,5%	
Assay (HPLC)	97,9 %	92,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity B	0,49 %	<=2,0 %	
Impurity C	0,82 %	<= 4,0 %	
Any other impurity	0,19 %	<= 0,5 %	
Total impurities	2,6 %	<= 6,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	< 60 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: 27/03/2024

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00124 ZHEJIANG TIANAI PHARMACEUTICAL, Co. Ltd.

Manufacturer batch: K-240111B

Product	Name	Capacity	Batch
1119574	CLINDAMICINA CLORHIDRATO	5 g	240613-E-1

1119574	CLINDAMICINA CLORHIDRATO	5 g	240613-E-2
1119574	CLINDAMICINA CLORHIDRATO	5 g	240613-E-3
1119576	CLINDAMICINA CLORHIDRATO	25 g	240613-G-2
1119576	CLINDAMICINA CLORHIDRATO	25 g	240613-G-3
1119576	CLINDAMICINA CLORHIDRATO	25 g	240613-G-4
1119577	CLINDAMICINA CLORHIDRATO	100 g	240613-J-2
1119577	CLINDAMICINA CLORHIDRATO	100 g	240613-J-3
1119577	CLINDAMICINA CLORHIDRATO	100 g	240613-J-4
1119580	CLINDAMICINA CLORHIDRATO	1 kg	240613-P-1
1370039	CLINDAMICINA CLORHIDRATO (FLB)	100 g	240613-J-1
1370041	CLINDAMICINA CLORHIDRATO (FLB)	25 g	240613-G-1
1370043	CLINDAMICINA CLORHIDRATO (FLB)	1 g	240613-D-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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