



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 260829**

Product:	CLINDAMYCIN HYDROCHLORIDE
Lot:	260829
Expiry date:	01/02/2029
Reference:	Cumple PhEur12.2
Synonyms:	
Formule:	C <sub>18</sub> H <sub>34</sub> Cl <sub>2</sub> N <sub>2</sub> O <sub>5</sub> S
Poids moléculaire:	461,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,D)	Test PhEur (A,D)	
Organoleptic properties	Conform	PhEur	
pH	4,3	3,0-5,0	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+143	(+135°)-(+150°)	
Moisture	4,0 %	3,0 - 6,0 %	
Sulphated ashes	0,00 %	<= 0,5%	
Assay (HPLC)	98,2 %	92,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity B	0,06 %	<= 2,0 %	
Impurity C	0,79 %	<= 4,0 %	
Any other impurity	0,08 %	<= 0,5 %	
Total impurities	1,1 %	<= 6,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#
Nitrosamine impurities	Conform		#

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: 11/06/2026

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00453 ZHEJIANG TIANAI PHARMACEUTICAL, Co. Ltd.

Manufacturer batch: K-20260201B

Produit	Nom	Capacité	Lot
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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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