

## Clindamycin HCL

<b>CODE ARTICLE:</b> 87898	<b>BATCH:</b> 0129866	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 17/07/2024	<b>TEST:</b> QC-00266547	
<b>EXPIRY DATE:</b> 02/04/2027	<b>FABRICATION DATE:</b> 02/04/2024	<b>MR:</b> 461,50
<b>CAS:</b> [21462-39-5]	<b>FORMULA:</b> C <sub>18</sub> H <sub>33</sub> CIN <sub>2</sub> O <sub>5</sub> S·HCl	
<b>SYNONYMS / BOTANICAL NAME:</b> CLINDAMYCIN CHLORHYDRATE; CLINDAMYCINE CHLORHYDRATE;		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			WHITE CRYSTALLINE POWDER	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE		VERY SOLUBLE IN WATER			PH.EUR.*
SOLUBLE		SLIGHTLY SOLUBLE IN ETHANOL 96°			PH.EUR.*
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	PASS				PH.EUR.*
CHLORIDE	PASS				PH.EUR.*
ROTAC.ESPECIFICA (BASE ANHIDRA)	140 -		135	150	PH.EUR.*
PH	4,3 -		3	5	PH.EUR.*
<b>RELATED SUBSTANCES</b>					
IMPURITY B	0,1 %			<=2,0	PH.EUR.*
IMPURITY C	0,8 %			<=4,0	PH.EUR.*
UNSPECIFIED IMPURITIES	0,3 %			<=0,5	PH.EUR.*
TOTAL IMPURITIES	1,1 %			<=6,0	PH.EUR.*
WATER	3,9 %		3	6	PH.EUR.*
SULPHATED ASHES	0,02 %		-	0,5	PH.EUR.*
ASSAY (ANHIDROUS BASIS)	97,4 %		92	102	PH.EUR.*
<b>RESIDUAL SOLVENTS</b>					
ETHANOL	N.D. MG/KG			<=5000	Manufacture's Standard
ACETONE	186 MG/KG			<=5000	Manufacture's Standard
CHLOROFORM	N.D. MG/KG			<=60	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				

*NON-sterile*



**Silvia Sancho-Tello Ripoll**  
Technical Director.

**The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE**

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 44077 Z. T. PHARMACEUTICAL CO., LTD. (China) Manufacturer Batch: K-240401B Manufacturer original CoA available under request

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