

Clindamycin HCL

CODE ARTICLE: 93340	BATCH: 0131443	Active pharmaceutical ingredient
TEST DATE: 17/07/2024	TEST: QC-00266547	
EXPIRY DATE: 02/04/2027	FABRICATION DATE: 02/04/2024	MR: 461,50
CAS: [21462-39-5]	FORMULA: C18H33ClN2O5S·HCl	
SYNONYMS / BOTANICAL NAME: CLINDAMYCIN CHLORHYDRATE; CLINDAMYCINE CHLORHYDRATE;		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			WHITE CRYSTALLINE POWDER	PH.EUR.*
SOLUBILITY					
SOLUBLE	VERY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN ETHANOL				PH.EUR.*
	96°				
IDENTIFICATION					
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.*
RELATED SUBSTANCES					
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 (ANHYDROUS BASIS)	97,4 %		92	102	PH.EUR.*
RESIDUAL SOLVENTS					
ETHANOL	N.D. ppm			<=5000	Manufacture's Standard
ACETONE	186 ppm			<=5000	Manufacture's Standard
CHLOROFORM	N.D. ppm			<=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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