

Clindamycin HCL

CODE ARTICLE: 93340	BATCH: 0121422	Active pharmaceutical ingredient
TEST DATE: 05/09/2023	TEST: QC-00256215	
EXPIRY DATE: 01/05/2026	FABRICATION DATE: 01/05/2023	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	CONFORM	-		CRYSTAL WHITE POWDER	PH.EUR.*
SOLUBILITY					
SOLUBLE	VERY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
CHLORIDE	CONFORM				PH.EUR.*
ROTAC.ESPECIFICA (BASE ANHIDRA)	137	-	135	150	PH.EUR.*
PH	4,3	-	3	5	PH.EUR.*
RELATED SUBSTANCES					
IMPURITY B	0,6	%		<=2,0	PH.EUR.*
IMPURITY C	0,8	%		<=4,0	PH.EUR.*
UNSPECIFIED IMPURITIES	0,3	%		<=0,5	PH.EUR.*
TOTAL IMPURITIES	2,0	%		<=6,0	PH.EUR.*
WATER	3,9	%	3	6	PH.EUR.*
SULPHATED ASHES	0,04	%	-	0,5	PH.EUR.*
ASSAY (ANHIDROUS BASIS)	98,2	%	92	102	PH.EUR.*
RESIDUAL SOLVENTS					
ETHANOL	N.D.	MG/KG		<=5000	Manufacture's Standard
ACETONE	160	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	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.



Silvia Sancho-Tello Ripoll
Technical Director.

This product has been manipulated in a NON-sterile clean room, for batches suitable for sterile use, consult availability.

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-230501B Manufacturer original CoA available under request

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