

Vancomycin HCL

CODE ARTICLE: 9190	BATCH: 0134896	Active pharmaceutical ingredient
TEST DATE: 28/02/2025	TEST: QC-00273186	
EXPIRY DATE: 15/10/2026	FABRICATION DATE: 16/10/2024	MR: 1486,00
CAS: [1404-93-9]	FORMULA: C ₆₆ H ₇₅ Cl ₂ N ₉ O ₂₄ *HCl	
STORAGE: Conservare a 2-8°C , al riparo dalla luce. (Store in tightly closed containers between 2 and 8 ° C.)		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS			POWDER	PH.EUR.*
COLOUR	PASS			WHITE	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	PRACTICALLY INSOLUBLE IN ETHANOL (96)				PH.EUR.*
<u>IDENTIFICATION</u>					
IDENTIFICATION A	PASS				PH.EUR.*
IDENTIFICATION B	PASS				PH.EUR.*
<u>DISSOLUTION ASPECT</u>					
DISSOLUTION ASPECT	PASS -			Clear	PH.EUR.*
ABSORBANCE (450nm)	<0,10 -			0,10	PH.EUR.*
ABSORBANCE (370nm)	<0,65 -			0,65	PH.EUR.*
PH	2,9 -		2,5	4,5	PH.EUR.*
WATER	2,3 %		0,0	5	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
IMPURITY A	0,1 %		-	3	PH.EUR.*
IMPURITY B+E	<DL (0,10%) -		-	2,0	PH.EUR.*
IMPURITY H	1 %		-	3	PH.EUR.*
IMPURITY J	0,6 %			<=1,6	PH.EUR.*
IMPURITY D	0,2 %		-	1,5	PH.EUR.*
IMPURITY F	0,5 %		-	1,5	PH.EUR.*
IMPURITY M	0,1 %		-	1,5	PH.EUR.*
IMPURITY G	0,1 %		-	1,2	PH.EUR.*
IMPURITY I	0,4 %		-	1,2	PH.EUR.*
IMPURITY C	0,1% -		-	1	PH.EUR.*
IMPURITY K	0,4 %			<=1,2	PH.EUR.*
UNKNOWN IMPURITIES RRT<1	0,4 %		-	0,8	PH.EUR.*
NUMBER OF UNKNOWN IMPURITIES WITH RRT<1 AND >0.30%	2 -		-	5	PH.EUR.*
UNKNOWN IMPURITIES RRT<1	0,6 %		-	0,8	PH.EUR.*
NUMBER OF UNKNOWN IMPURITIES WITH RRT>1 AND >0.30%	1 -		-	3	PH.EUR.*
TOTAL IMPURITIES	5,7 %		-	9	PH.EUR.*
VANCOMYCIN B	94,3 %		91	-	PH.EUR.*
SULPHATED ASH	0,2 %		0,0	1	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	1120 ui/mg		1.050	-	PH.EUR.*
PROTEINS	436 ppm		0,0	5.000	Manufacture's Standard
<u>MICROBIOLOGICAL CONTROL</u>					
TOTAL AEROBICS	<1 UFC/G			1000	Manufacture's Standard

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: 45291 L. G. F. F. PHARMACEUTICAL CO. LTD. (China) Manufacturer Batch: HAP2410014EA Manufacturer original CoA available under request

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TEST	RESULTS	Units	MIN	MAX	METHOD
MOLDS AND YEASTS	<1	UFC/G		100	Manufacture's Standard
RESIDUAL SOLVENTS					
ETANOL	41	ppm		5000	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	PASS				
Risk Assessment Evaluation for Nitrosamines	PASS				

NON-sterile



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

Silvia Sancho-Tello Ripoll
Technical Director.

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