

Vancomycin HCL

CODE ARTICLE: 9190	BATCH: 0120557	Active pharmaceutical ingredient
TEST DATE: 10/07/2023	TEST: QC-00255126	
EXPIRY DATE: 07/05/2025	FABRICATION DATE: 08/05/2023	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	CONFORM			POWDER	PH.EUR.*
COLOUR	CONFORM			WHITE	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	PRACTICALLY INSOLUBLE IN ETHANOL (96)				PH.EUR.*
<u>IDENTIFICATION</u>					
IDENTIFICACION A	CONFORM				PH.EUR.*
IDENTIFICACION B	CONFORM				PH.EUR.*
<u>DISSOLUTION ASPECT</u>					
DISSOLUTION ASPECT	CONFORM -			Límpida	PH.EUR.*
ABSORBANCIA (450nm)	<0,10 -			0,10	PH.EUR.*
ABSORBANCIA (370nm)	<0,65 -			0,65	PH.EUR.*
PH	2,9 -		2,5	4,5	PH.EUR.*
WATER	2,5 %		0,0	5	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
IMPURITY A	0,2 %		-	3	PH.EUR.*
IMPUREZA B+E	<DL (0,10%) -		-	2,0	PH.EUR.*
IMPURITY H	1,1 %		-	3	PH.EUR.*
IMPURITY J	0,5 %		-	1,6	PH.EUR.*
IMPURITY D	0,1 %		-	1,5	PH.EUR.*
IMPURITY F	0,4 %		-	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	<DL (0,10%) %		-	1	PH.EUR.*
IMPURITY K	0,4 %		-	1,2	PH.EUR.*
IMPUREZAS DESCONOCIDAS RRt<1	0,3 %		-	0,8	PH.EUR.*
NUMERO DE IMPUREZAS DESCONOCIDAS CON RRt<1 y >0,30%	1 -		-	5	PH.EUR.*
IMPUREZAS DESCONOCIDAS RRt>1	0,6 %		-	0,8	PH.EUR.*
NUMERO DE IMPUREZAS DESCONOCIDAS CON RRt>1 y >0,30%	1 -		-	3	PH.EUR.*
TOTAL IMPURITIES	5 %		-	9	PH.EUR.*
VANCOMYCIN B	95 %		91	-	PH.EUR.*
SULPHATED ASH	0,1 %		0,0	1	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	1155,89 ui/mg		1.050	-	PH.EUR.*
PROTEINS	486 ppm		0,0	5.000	Manufacture's Standard

MICROBIOLOGICAL CONTROL

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: HAP2305001EA Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



Vancomycin HCL

CODE ARTICLE: 9190	BATCH: 0120557	Active pharmaceutical ingredient
TEST DATE: 10/07/2023	TEST: QC-00255126	
EXPIRY DATE: 07/05/2025	FABRICATION DATE: 08/05/2023	MR: 1486,00
CAS: [1404-93-9]	FORMULA: C66H75Cl2N9O24*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
TOTAL AEROBICS	<1	UFC/G		1000	Manufacture's Standard
MOLDS AND YEASTS	<1	UFC/G		100	Manufacture's Standard
RESIDUAL SOLVENTS					
ETANOL	151	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				

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



Silvia Sancho-Tello Ripoll
Technical Director.

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: HAP2305001EA Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com

