

Vancomycin hydrochloride

CODE ARTICLE: 11704	BATCH: 0123809	Active pharmaceutical ingredient
TEST DATE: 05/12/2023	TEST: QC-00259302	
EXPIRY DATE: 08/09/2025	FABRICATION DATE: 09/09/2023	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.*
SOLUBILITY					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	PRACTICALLY INSOLUBLE IN ETHANOL (96)				PH.EUR.*
IDENTIFICATION					
IDENTIFICACION A	CONFORM				PH.EUR.*
IDENTIFICACION B	CONFORM				PH.EUR.*
DISSOLUTION ASPECT					
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	2,3 %		0,0	5	PH.EUR.*
RELATED SUBSTANCES					
IMPURITY A	0,2 %		-	3	PH.EUR.*
IMPUREZA B+E	<DL (0,10%) -		-	2,0	PH.EUR.*
IMPURITY H	1 %		-	3	PH.EUR.*
IMPURITY J	0,4 %		-	1,6	PH.EUR.*
IMPURITY D	0,1 %		-	1,5	PH.EUR.*
IMPURITY F	0,4 %		-	1,5	PH.EUR.*
IMPURITY M	<DL (0,10%) -		-	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	0,5 %		-	0,8	PH.EUR.*
NUMERO DE IMPUREZAS DESCONOCIDAS CON RRt>1 y >0,30%	1 -		-	3	PH.EUR.*
TOTAL IMPURITIES	4,5 %		-	9	PH.EUR.*
VANCOMYCIN B	95,5 %		91	-	PH.EUR.*
SULPHATED ASH	0,1 %		0,0	1	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	1139 ui/mg		1.050	-	PH.EUR.*
PROTEINS	1318 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: HAP2309001EA 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 hydrochloride

CODE ARTICLE: 11704	BATCH: 0123809	Active pharmaceutical ingredient
TEST DATE: 05/12/2023	TEST: QC-00259302	
EXPIRY DATE: 08/09/2025	FABRICATION DATE: 09/09/2023	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
TOTAL AEROBICS	<1	UFC/G		1000	Manufacture's Standard
MOLDS AND YEASTS	<1	UFC/G		100	Manufacture's Standard
RESIDUAL SOLVENTS					
ETANOL	57	ppm		5000	Manufacture's Standard



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

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: HAP2309001EA 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

