



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233238

Product:	VANCOMYCIN HYDROCHLORIDE
Lot:	233238
Expiry date:	22/03/2025
Reference:	Cumple PhEur11.2
Synonyms:	
Formule:	C ₆₆ H ₇₅ Cl ₂ N ₉ O ₂₄ ·HCl
Poids moléculaire:	1486 g/mol

Assay	Result	Specification	
Identification	Conform(A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
pH	3,2	2,5 - 4,5	
Vancomycin B (UPLC)	94,5 %	>= 91,0 %	
Related substances (UPLC)	Conform	Test PhEur	
STORE IN REFRIGERATOR (2-8°C)			
Elemental impurities	Conform	Test PhEur	#
Water	2,1 %	<= 5,0 %	
Sulphated ashes	0,03 %	<= 1,0 %	
Antimicrobial power	1097 UI/mg sps	> 1050 UI/mg sps	
Impurity A	< 0,10 %	<= 3,0 %	
Impurity H	1,6 %	<= 3,0 %	
Impurities B+E	< 0,10 %	<= 2,0 %	
Impurity J	0,6 %	<= 1,6 %	
Impurity D	0,1 %	<= 1,5 %	
Impurity F	0,6 %	<= 1,5 %	
Impurity M	0,1 %	<= 1,5 %	
Impurity G	0,1 %	<= 1,2 %	
Impurity I	0,5 %	<= 1,2 %	
Impurity K	0,3 %	<= 1,2 %	
Impurity C	0,1 %	<= 1,0 %	
Any other impurity eluting before Vancomycin B	0,2 %; 0 imp >= 0,30 %	<= 0,8% máx. 5 Imp >= 0,30%	
Any other impurity eluting after Vancomycin B	0,6 %; 1 imp >= 0,30%	<= 0,8% máx. 3 Imp >= 0,30%	
Total impurities	5,5 %	<= 9,0 %	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics:

Conservation: In airtight containers. Protect from light. FRIDGE (2-8°C)

Date of analysis: 21/08/2023

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00091

Manufacturer batch: HAP2303020EB

Produit	Nom	Capacité	Lot
1193037	VANCOMICINA CLORHIDRATO	1 kg	233238-P-1
1193037	VANCOMICINA CLORHIDRATO	1 kg	233238-P-2
1193038	VANCOMICINA CLORHIDRATO	50 g	233238-I-1
1193038	VANCOMICINA CLORHIDRATO	50 g	233238-I-2
1193039	VANCOMICINA CLORHIDRATO	250 g	233238-N-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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