



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 233907**

Product:	VANCOMYCIN HYDROCHLORIDE
Lot:	233907
Expiry date:	28/09/2025
Reference:	Cumple PhEur11.3
Synonyms:	
Formule:	C <sub>66</sub> H <sub>75</sub> Cl <sub>2</sub> N <sub>9</sub> O <sub>24</sub> ·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	2,8	2,5 - 4,5	
Vancomycin B (UPLC)	95,5 %	>= 91,0 %	
Related substances (UPLC)	Conform	Test PhEur	
STORE IN REFRIGERATOR (2-8°C)			
Elemental impurities	Conform	Test PhEur	#
Water	2,0 %	<= 5,0 %	
Sulphated ashes	0,05 %	<= 1,0 %	
Antimicrobial power	1088 UI/mg sps	>= 1050 UI/mg sps	
Impurity A	0,2 %	<= 3,0 %	
Impurity H	1,1 %	<= 3,0 %	
Impurities B+E	< 0,10 %	<= 2,0 %	
Impurity J	0,4 %	<= 1,6 %	
Impurity D	0,1 %	<= 1,5 %	
Impurity F	0,3 %	<= 1,5 %	
Impurity M	< 0,10 %	<= 1,5 %	
Impurity G	0,1 %	<= 1,2 %	
Impurity I	0,4 %	<= 1,2 %	
Impurity K	0,4 %	<= 1,2 %	
Impurity C	0,1 %	<= 1,0 %	
Any other impurity eluting before Vancomycin B	0,3%;1 imp >=0,30 %	<=0,8% máx. 5 Imp >=0,30%	
Any other impurity eluting after Vancomycin B	0,5 %;1 imp >=0,30 %	<=0,8% máx. 3 Imp >=0,30%	
Total impurities	4,5 %	<= 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)

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Date of analysis: 09/02/2024

Judgement:  
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00091

Manufacturer batch: HAP2309014EA

Produit	Nom	Capacité	Lot
1193030	VANCOMICINA CLORHIDRATO	5 kg	233907-Q-1
1193037	VANCOMICINA CLORHIDRATO	1 kg	233907-P-1
1193038	VANCOMICINA CLORHIDRATO	50 g	233907-I-1
1193039	VANCOMICINA CLORHIDRATO	250 g	233907-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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