METAPHARMACEUTICAL IND SL
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VANCOMICINA HCL (EUR. PH.)

PRODUCT CODE: 02964	CAS Nº: 1404-93-9	ANALYSIS Nº: 322/24	
MANUFACTURER BATCH:	HVN2409208E	CERTIFICATE ID:	44.519
SUPPLIER BATCH:	----	MANUFACTURING DATE:	23/09/2024
METAPH BATCH:	0091224	EXPIRY DATE:	22/09/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, very hygroscopic powder	Almost white, very hygroscopic powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution		
Clear	Complies	Complies
Absorbance		
450 nm	=< 0.10	0.02
370 nm	=< 0.65	0.09
pH	2.5 - 4.5	2.8
Related substances		
Vancomycin B	=> 91.0 %	97.7 %
Impurity A	=< 3.0 %	0.2 %
Impurity H	=< 3.0 %	0.4 %
Impurity B + E	=< 2.0 %	0.2 %
Impurity J	=< 1.6 %	0.4 %
Impurity D	=< 1.5 %	< 0.1 %
Impurity F	=< 1.5 %	0.3 %
Impurity M	=< 1.5 %	< 0.1 %
Impurity G	=< 1.2 %	< 0.1 %
Impurity I	=< 1.2 %	0.1 %
Impurity K	=< 1.2 %	0.4 %
Impurity C	=< 1.0 %	< 0.1 %
Any other impurity eluting before vancomycin B		
Each impurity	=< 0.8 %	< 0.8 % (#)
Not more than 5 such impurities > 0.3 %	Complies	Complies
Any other impurity eluting after vancomycin B		
Each impurity	=< 0.8 %	< 0.1 %
Not more than 3 impurities > 0.3 %	Complies	Complies
Total of impurities	=< 9.0 %	2.1 %
Water	=< 5.0 %	3.6 %
Sulfated ash	=< 1.0 %	0.04 %
Assay	=> 1050 IU/mg	1111.2 UI/mg

COMPLIES WITH

European Pharmacopeia 11.0

Analysis date: 25/02/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000447
NORTH CHINA PHARMACEUTICAL HUASHENG Co., Ltd.
No.8 Yangzi Road,
Shijiazhuang Economic & Technical Development

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REMARKS

(#) Impurities detailed underneath:
RT (18.04 min) = 0.1 %
RT (26.68 min) = 0.1 %

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Vancomycin hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed and protected from light at 2 - 8 ºC.

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