METAPHARMACEUTICAL

TECHNICAL DATA SHEET

02964-TDS-ENG-2025

VANCOMICINA HCL (EUR. PH.)		
DESCRIPTION DCI: VANCOMYCIN HYDROCHLORIDE		DESCRIPTION DOE: VANCOMICINA HIDROCLORURO
CAS Nº: 1404-93-9	EC Nº: 604-193-8	AEMPS CODE: 3197CH
MOL. WEIGHT: 1485,70	MOL. FORMULA: C66H76Cl3N9O24	ARTICLE CODE: 02964

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, very hygroscopic powder
Solubility	Freely soluble in water, practically insoluble in ethanol 96%
Identification A	Complies
Identification B	Complies
Appearance of solution	
Clear	Complies
Absorbance	
450 nm	=< 0.10
370 nm	=< 0.65
pH	2.5 - 4.5
Related substances	
Vancomycin B	=> 91.0 %
Impurity A	=< 3.0 %
Impurity H	=< 3.0 %
Impurity B + E	=< 2.0 %
Impurity J	=< 1.6 %
Impurity D	=< 1.5 %
Impurity F	=< 1.5 %
Impurity M	=< 1.5 %
Impurity G	=< 1.2 %
Impurity I	=< 1.2 %
Impurity K	=< 1.2 %
Impurity C	=< 1.0 %
Any other impurity eluting before vancomycin B	
Each impurity	=< 0.8 %
Not more than 5 such impurities > 0.3 %	Complies
Any other impurity eluting after vancomycin B	
Each impurity	=< 0.8 %
Not more than 3 impurities > 0.3 %	Complies
Total of impurities	=< 9.0 %

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ATTRIBUTES	SHOULD BE
Water	=< 5.0 %
Sulfated ash	=< 1.0 %
Assay	=> 1050 IU/mg
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
E. Coli	Absence/1g
C. Albicans	Absence/1g
S. Aureus	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

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

REMARKS

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

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.

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