

Certificate of Analysis

Product name: **Vancomycini hydrochloridum**

Batch number / Weight: **23I28-B13-235545 / 5 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23I28-B13 / INS-23-9596**

Reference Code / No.: **V01681 / HAP2306001EA**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white powder	Conform		
Identification A	Conform	Conform		
Identification B	White	Conform		
Appearance of solution	Clear	Conform		
Absorbance	A 450 nm ≤ 0,10	<0,10		
Absorbance	A 370 nm ≤ 0,65	<0,65		
pH	2,5 - 4,5	3,1		
Vancomycin B	≥ 91,0	94,0	%	
Related substances	Conform	Conform		
Impurity A	≤ 3,0	0,2	%	
Impurity H	≤ 3,0	1,2	%	
Sum impurities B and E	< 2,0	<0,10	%	
Impurity J	≤ 1,6	0,5	%	
Impurity D	≤ 1,5	0,1	%	
Impurity F	≤ 1,5	0,5	%	
Impurity M	≤ 1,5	0,1	%	
Impurity G	≤ 1,2	<0,10	%	
Impurity I	≤ 1,2	0,5	%	
Impurity K	≤ 1,2	0,4	%	
Impurity C	≤ 1,0	<0,10	%	
Any other impurity RT < Vanc.	≤ 0,8	0,3	%	
Any other impurity RT > Vanc.	≤ 0,8	0,5	%	
no.of impurities < Vanc.B > 0.30%	≤ 5	Conform		
no.of impurities > Vanc.B > 0.30%	≤ 3	Conform		
Total impurities	≤ 9,0	5,1	%	
Water (Karl Fischer)	≤ 5,0	3,8	%	
Sulphated ash	≤ 1,0	0,12	%	

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Metallic residues	CHMP/ICH/353369/2013	Conform	Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform	Data producer
Assay Vancomycine hydrochlorid	≥ 1050	1248	IU / mg
Endotoxins	$\leq 0,25$	$< 0,25$	IU / mg
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform	Data producer
Total aerobic microbial count (TA)	$\leq 10^3$	< 1	CFU/g
Total yeasts and moulds (TYMC)	$\leq 10^2$	< 1	CFU/g

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Quercus, ElSpol, CBM, FapI

Release:

Agnieszka Pszczółka

Qualified Person

06-02-2024

Expiration: 21-06-2025

Conclusion: APPROVED

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