

Certificate of Analysis

Product name: **Vancomycini hydrochloridum**

Batch number / Weight: **22B15-B06-217556 / 100 G**

Analysed according to: **Ph. Eur. 01/2022:0359**

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	0,06		
Absorbance	A 370 nm ≤ 0,65	0,33		
pH	2,5 - 4,5	3,07		
Vancomycin B	≥ 91,0	94,9	%	
Related substances	Conform	Conform		
Impurity A	≤ 3,0	0,20	%	
Impurity H	≤ 3,0	0,95	%	
Sum impurities B and E	≤ 2,0	0,12	%	
Impurity J	≤ 0,2	0,80	%	
Impurity D	≤ 1,5	0,18	%	
Impurity F	≤ 1,5	0,45	%	
Impurity M	≤ 1,5	< 0,1	%	
Impurity G	≤ 1,2	< 0,1	%	
Impurity I	≤ 1,2	0,37	%	
Impurity K	≤ 1,2	0,42	%	
Impurity C	≤ 1,0	0,11	%	
Any other impurity RT < Vanc.	≤ 0,8	0,26	%	
Any other impurity RT > Vanc.	≤ 0,8	0,49	%	
Total impurities	≤ 9,0	5,08	%	
Water (Karl Fischer)	≤ 5,0	2,64	%	
Sulphated ash	≤ 1,0	0,09	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Vancomycine hydrochlorid	≥ 1050	1053,184	IU / mg	
Endotoxins	≤ 0,25	< 0,25	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	≤ 10 ³	< 10	CFU/g	
Total yeasts and moulds (TYMC)	≤ 10 ²	< 10	CFU/g	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

30-05-2022

Expiration: 24-09-2023

Conclusion: APPROVED

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