Certificate of Analysis

Product name: Vancomycini hydrochloridum
Batch number / Weight: 25B03-B05-006757 / 100 g
Analyzed according to: Ph. Eur. 11.6
Number of Analysis / Certificate no.: 25B03-B05 / QO0011370
Reference code / No.: V01681 / HAP2411006EB

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, very hygroscopic powder	Conform		
Identification	A,B	Conform		
Appearance of solution	Clear	Conform		
Absorbance	A 450 nm<=0,10 / A 370 nm<=0,65	0,024 / 0,129		
pH	0,00 - 7,00	2,81		
Vancomycin B	>=91,0	94,54	%	
Related substances	Conform	Conform		
Impurity A	<=3,0	0,14	%	
Impurity H	<=3,0	0,96	%	
Sum impurities B and E	<=2,0	0,07	%	
Impurity J	<=1,6	0,48	%	
Impurity D	<=1,5	0,14	%	
Impurity F	<=1,5	0,43	%	
Impurity M	<=1,5	0,09	%	
Impurity G	<=1,2	0,08	%	
Impurity I	<=1,2	0,45	%	
Impurity K	<=1,2	0,29	%	
Impurity C	<=1,0	0,07	%	
Any other impurity RT < Vanc.	<=0,8	0,33	%	
Any other impurity RT > Vanc.	<=0,8	0,55	%	
no.of impurities <Vanc.B>0.30%	<=5	Conform		
no.of impurities >Vanc.B>0.30%	<=3	Conform		
Total impurities	<=9,0	5,50	%	
Water (Karl Fischer)	<= 5,0	2,30	% m/m	
Sulfated ash	<=1,0	0,11	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	>=1050	1083	IU/mg	
Endotoxins	<=0,25	<0,13	IU/mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP
TAMC	<=10^3	<10^3	cfu/g	

Fagron Services Northern Europe sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia
Poland

T: +48 12 3343 512
F: +48 12 3343 513
fsne@fagron.pl
www.fagron.pl

NIP: 6772437042
REGON: 381033027
KRS: 0000740604
BDO: 000601440

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	Requirement	Result	Unit	Standard remark
TYMC	<=10^2	<10^1	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 FSNE

Release:

26-3-2025
Ewelina Gadzinowska
Qualified Person

Expiration: 16-11-2026
Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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