Certificate of Analysis

Product name: Vancomycini hydrochloridum
Batch number / Weight: 25K18-B01-017565 / 100 g
Producer / Producer Batch Number: Livzon Group Fuzhou Fuxing Pharma. Co., Ltd. / HAP2510011EB
Analyzed according to: Ph.Eur.12.1
Number of Analysis / Certificate no.: 25K18-B01 / QO0025449

	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	0,014		
Absorbance	A 370 nm<=0,65	0,073		
pH	2,5-4,5	2,99		
Vancomycin B	>=91,0	94,56	%	
Related substances	Conform	Conform		
Impurity A	<=3,0	0,18	%	
Impurity H	<=3,0	0,95	%	
Sum of impurities B and E	<=2,0	<0,10	%	
Impurity J	<=1,6	0,30	%	
Impurity D	<=1,5	<0,10	%	
Impurity F	<=1,5	0,60	%	
Impurity M	<=1,5	<0,10	%	
Impurity G	<=1,2	<0,10	%	
Impurity I	<=1,2	0,27	%	
Impurity K	<=1,2	0,42	%	
Impurity C	<=1,0	<0,10	%	
Any other impurity RT < Vanc.	<=0,8	0,33	%	
Any other impurity RT > Vanc.	<=0,8	0,61	%	
no. of impurities (RT>Vanc. B) >0.30%	<=3	1		
Total impurities	<=9,0	5,40	%	
Water	<= 5,0	1,6		
Sulfated ash	<=1,0	0,10	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	>=1050	1088	IU/mg	
Endotoxins	<=0,25	<0,13	IU/mg	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	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

Release:

9-1-2026
Agnieszka Pszczółka
Qualified Person

Expiration: 19-10-2027
Conclusion: APPROVED

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

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