

Certificate of Analysis

Product name: Vancomycini hydrochloridum
Batch number / Weight: 25D28-B13-014021 / 10 g
Producer / Producer Batch Number: Livzon Group Fuzhou Fuxing Pharma. Co., Ltd. / HAP2503005EB
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25D28-B13 / QO0020401

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white very hygroscopic powder	Conform		
Identification	A,B	Conform		
Appearance of solution	Clear	Conform		
Absorbance	<=0,10	Conform		
Absorbance	A 450 nm<=0,10	0		
Absorbance	A 370 nm<=0,65	0		
pH	0,00 - 7,00	2,76		
Vancomycin B	>=91,0	94,63	%	
Related substances	Conform	Conform		
Impurity A	<=3,0	0,09	%	
Impurity H	<=3,0	1,23	%	
Sum impurities B and E	<=2,0	0,04	%	
Impurity J	<=1,6	0,37	%	
Impurity D	<=1,5	0,10	%	
Impurity F	<=1,5	0,47	%	
Impurity M	<=1,5	0,10	%	
Impurity G	<=1,2	0,07	%	
Impurity I	<=1,2	0,41	%	
Impurity K	<=1,2	0,38	%	
Impurity C	<=1,0	0,05	%	
Any other impurity RT < Vanc.	<=0,8	0,33	%	
Any other impurity RT > Vanc.	<=0,8	0,55	%	
no. of impurities (RT<Vanc. B) >0.30%	<=5	1		
no. of impurities (RT>Vanc. B) >0.30%	<=3	1		
Total impurities	<=9,0	0,00	%	
Water (Karl Fischer)	<= 5,0	0,00	% m/m	
Sulfated ash	<=1,0	0,20	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	>=1050	0,00	% m/m	
Endotoxins	<=0,25	< 0,13	IU/mg	

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TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
TAMC	$\leq 10^3$	$< 10^3$	cfu/g	
TYMC	$\leq 10^2$	$< 10^1$	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:

14-8-2025

Ewelina Gadzinowska

Qualified Person

Expiration: 16-3-2027

Conclusion: APPROVED

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