

Certificate of Analysis

Product name: Vancomycin hydrochloride
Number of analysis: T0009020
Batch number / Weight: 24K26-H01-00652 / 10g
Producer / Producer Batch Number: Livzon Group Fuzhou Fuxing Pharmaceutical Co Ltd/HAP2407021EB
Analysed according to: PH.EUR 11.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, very hygroscopic powder.	Conform		
Solubility	Freely soluble in water, practically insoluble in ethanol (96 per cent)	Conform		
Identification A	Conform	Conform		Vancomycin B and related substances; HPLC
Identification B	Conform	Conform		Reaction (a) of chlorides
Appearance of solution	Clear	Conform		10% <i>m/V</i> H ₂ O
Appearance of solution	<= 0,10	Conform		10% <i>m/V</i> H ₂ O; absorbance at 250nm
pH	2,5 - 4,5	2,53		5% <i>m/V</i> H ₂ O
Water	<=5,0	0,33	%	
Vancomycin B and related substances	Conform	Conform		HPLC
Vancomycin B	>= 91,0	93,83	%	HPLC
Impurity A	<= 3,0	0,2	%	HPLC
Impurity H	<= 3,0	1,13	%	HPLC
Sum of impurities B and E	<= 2,0	0,06	%	HPLC
Impurity J	<= 1,6	0,48	%	HPLC
Impurity D	<= 1,5	0,16	%	HPLC
Impurity F	<= 1,5	0,54	%	HPLC
Impurity M	<= 1,5	0,12	%	HPLC
Impurity G	<= 1,2	0,19	%	HPLC
Impurity I	<= 1,2	0,42	%	HPLC
Impurity K	<= 1,2	0,30	%	HPLC
Impurity C	<= 1,0	0,10	%	HPLC
Any other impurity eluting before Vancomycin B	<= 0,8	0,31	%	HPLC
Any other impurity eluting after Vancomycin B	<= 0,8	0,64	%	HPLC
Total impurities	<= 9,0	6,2	%	HPLC
Sulfated ash	<= 1,0	0,21	%	
Assay	>= 1050	1088	IU/mg	Anhydrous basis
Residual solvents	Conform	Conform		
Ethanol	<=5000	70	ppm	
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		



Analysis performed by the authorized internal lab.

Release:

Konstantina Tziolia

Pharmacist - QA Manager / QP

28/11/2024

Expiration: 20-07-2026

Conclusion: APPROVED

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