

METAPHARMACEUTICAL

N DE LOTE:

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NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD. CERTIFICATE OF ANALYSIS

Add: No. 8 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei 052160, China
Tel: +86-311-83090290 Fax: +86-311-83090280 Website: <http://www.ncpchs.com> E-mail: mail@ncpchs.com

gh
18/11/2025

Product name : Vancomycin Hydrochloride

Batch No. :	HVN2509208E	Manuf. date :	2025.09.24
Cert. No. :	P-V-02	Report date :	2025.10.29
Batch size :	53.160kg	Retest date :	2028.09.23

Tests	Specifications	Results
Characters:	White or almost white powder	Almost white powder
Identification:	A The retention time of the principal peak in the chromatogram obtained with test solution(a) is similar to the reference solution, complies	Complies
	B Reaction(a) of chlorides, complies	Complies
Appearance of solution:	Clear	Clear
	The absorbance of the solution at 450nm is not greater than 0.10	0.012
pH:	2.5 to 4.5	2.9
Water :	Maximum 5.0%	2.5%
Sulfated ash	Maximum 1.0%	0.4%
Assay(microbial) (anhydrous substance):	Minimum 1050 IU/mg	1107 IU/mg
Bacterial endotoxins:	Less than 0.25 IU/mg	Complies
Vancomycin B:	Minimum 93.0%	96.2%
Related substances:	1)Any impurity: Maximum 4.0%	1.1%
	2)Total: Maximum 7.0%	3.8%
Microbial Limit Test:	TAMC is not more than 1000 CFU/g	<1 CFU/g
	TYMC is not more than 100 CFU/g	<1 CFU/g

Conclusion : Complies with Ph Eur 2.9.10

Reporter: 徐静 Manager of QC division: 张义

