



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

25 JUL 2024

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

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Product name : Vancomycin Hydrochloride

Batch No.	:	HVS2401202E	Manuf. date	:	2024.01.03
Cert. No.	:	P-V-01	Report date	:	2024.07.09
Batch size	:	44.080kg	Retest date	:	2027.01.02

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	0.009
pH:	2.5 to 4.5	2.7
Water:	Maximum 5.0%	1.4%
Sulfated ash:	Maximum 1.0%	0.1%
Assay(microbial) (anhydrous substance):	Minimum 1050 IU/mg	1083 IU/mg
Bacterial endotoxins:	Less than 0.25 IU/mg	Complies
Vancomycin B:	Minimum 93.0%	96.5%
Related substances:	1)Any impurity: Maximum 4.0%	1.1%
	2)Total: Maximum 7.0%	3.5%
Micobial TAMC:	Not more than 1000cfu/g	<100 cfu/g
TYMC:	Not more than 100cfu/g	<100 cfu/g

Conclusion : Complies with Ph Eur 9.0

Reporter: 徐静 Manager of QC division 杜军

Qualified Person:

