



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

Certificate of Analysis Finished Product

Product Name	VANCAN 500 Injection	A.R. No.	ARN/FP/25/004
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2521A	Sampled by	Anuj Verma
Batch Size	10,000 Vials	Sampled on	14/08/2025
Mfg. Date	08/2025	Date of Testing	16/08/2025
Exp. Date	07/2027	Date of Release	30/08/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	<p>A. In the test for Vancomycin B, the retention time of the principle peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.</p> <p>B. It gives reaction (A) of chloride.</p>	<p>Complies</p> <p>Complies</p>
3.	Appearance of solution	A 10% solution of Vancomycin hydrochloride is clear and the absorbance of the solution at 450 nm is not more than 0.1.	Complies
4.	Uniformity of Weight	Average weight $\pm 10\%$	-5.22% & +6.78%
5.	Average weight	Informative $\pm 2\%$.	535.9 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.78
7.	Vancomycin B	NLT 88.0%	99.167%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	0.82%
	Total impurities	NMT 12.0%	0.82%
9.	Water	NMT 5% w/w	2.02%w/w
10.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/vial	3049/vial 1/vial
	(B.) Visual Particle	Constitute the injection as directed on the label; The solution is essentially free from particles of foreign matter that can be seen on visual Inspection.	Complies

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN



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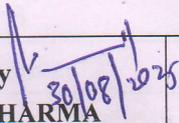
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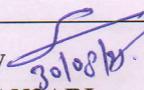
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11.	Sterility	No microbial growth should be observed.	Complies		
12.	Bacterial Endotoxins	NMT 2.5 EU/ml of Vancomycin.	Less than 2.5 EU/ml of Vancomycin.		
13.	Assay: (By Microbiology) Each glass vial Contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Vancomycin Hydrochloride(Sterile) IP Eq. to Vancomycin (As sterile freeze dried powder)		500 mg	500.458 mg	100.09%	90.0% to 115.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not~~ complies as per IP/BP/USP/HS.

Analysis by 
NAME: NIKHIL SHARMA

Checked by 
NAME: SUFIYAN ANSARI

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NAME: MRS. SWATI DHAWAN

