

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 Injection	A.R. No.	ARN/FP/25/096
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN25111A	Sampled by	Anuj Verma
Batch Size	10,000 Vials	Sampled on	16/02/2026
Mfg. Date	02/2026	Date of Testing	17/02/2026
Exp. Date	01/2028	Date of Release	03/03/2026

OS. 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	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. B. It gives reaction (A) of chloride.	Complies Complies
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 $\pm 10\%$	-2.36 & +3.16%
5.	Average weight	Informative $\pm 2\%$.	549.0 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.88
7.	Vancomycin B	NLT 88.0%	99.98%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	Not detected
	Total impurities	NMT 12.0%	Not detected
9.	Water	NMT 5% w/w	1.20%w/w
10.	Particulate Matter		
	(A.) Light Obscuration		
	Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	98/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/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

23/03/2026

Checked by

23/03/26

Approved by

23/03/26



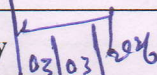
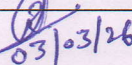
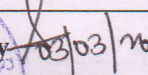
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11.	Sterility	No microbial growth should be observed.	Complies		
12.	Bacterial Endotoxins	NMT 2.5 EU/ml of Vancomycin.	Less than 2.5 EU/ml of Vancomycin.		
13.	Assay: (By Microbiology) Each glass vial Contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Vancomycin Hydrochloride (Sterile) IP Eq. to Vancomycin		500 mg	508.9424 mg	101.79%	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/PHS.

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: RAMANJEET SINGH	Approved by  NAME: MRS. SWATI DHAWAN
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