

**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/25/042
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2633A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	31/07/2026
Mfg. Date	07/2026	Date of Testing	01/08/2026
Exp. Date	06/2028	Date of Release	18/08/2026
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	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.	Complies
		B. It gives reaction (A) of chloride.	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.	0.038
4.	Uniformity of weight	Average weight $\pm 10\%$	-2.01 & +1.81%
5.	Average weight	Informative $\pm 2\%$.	5400.5 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.71
7.	Vancomycin B	NLT 88.0%	95.017%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	1.036%
	Total impurities	NMT 12.0%	4.983
9.	Water	NMT 5% w/w	2.09%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	2,636/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 18/08/26
NAME: NIKHIL SHARMAChecked by 18/08/26
NAME: SURJEET KAURApproved by 18/08/26
NAME: MRS. SWATI DHAWAN

**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/25/042
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2633A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	31/07/2026
Mfg. Date	07/2026	Date of Testing	01/08/2026
Exp. Date	06/2028	Date of Release	18/08/2026

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
Vancomycin Hydrochloride (Sterile) IP Eq. to Vancomycin		500 mg	516.0529mg	103.21%
				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/ITS~~.

Analysis by 18/08/26
NAME: NIKHIL SHARMAChecked by 18/08/26
NAME: SURJEET KAURApproved by 18/08/26
NAME: MRS. SWATI DHAWAN