



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/26/073
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2685A	Sampled by	Rakesh
Batch Size	4,820 Vials	Sampled on	01/09/2026
Mfg. Date	09/2026	Date of Testing	02/09/2026
Exp. Date	08/2028	Date of Release	16/09/2026

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. 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.	0.058%
4.	Uniformity of weight	Average weight $\pm 10\%$	-2.04 & +2.84%
5.	Average weight	Informative $\pm 2\%$.	554.6 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.86
7.	Vancomycin B	NLT 88.0%	95.605%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	1.153%
	Total impurities	NMT 12.0%	4.395%
9.	Water	NMT 5% w/w	2.61%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	2,119/vial 4/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

Name : Mrs. Swati Dhawan
Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology
Registration : 030598
Approved by :

Analysis by
NAME: MOHD. ZAID

Checked by
NAME: SURJEET KAUR

NAME: MRS. SWATI DHAWAN

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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	518.1465 mg	103.63%	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/HHS.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. 1607593593

Approved by

NAME: MRS. SWATI DHAWAN

Analysis by
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Checked by
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