

Title

:

Certificate of Analysis Finished Product

Product Name	VANCAN Injection	A.R. No.	ARN/FP/26/074
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2686A	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.	0.053%
4.	Uniformity of weight	Average weight $\pm 10\%$	-1.85 & +2.44%
5.	Average weight	Informative $\pm 2\%$.	548.0 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.86
7.	Vancomycin B	NLT 88.0%	95.590%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	1.146%
	Total impurities	NMT 12.0%	4.410%
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	2,545/vial 6/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

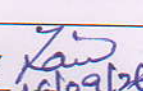
Name : Mrs. Swati Dhawan

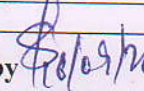
Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 13500009533

NAME: MRS. SWATI DHAWAN

Analysis by 
NAME: MOHD. ZAHID

Checked by 
NAME: SURJEET KAUR

Title

:

Certificate of Analysis Finished Product

Product Name	VANCAN Injection	A.R. No.	ARN/FP/26/074
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2686A	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

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	511.1462 mg	102.23%	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/THS.

Analysis by *Zaid*
NAME: MOHD. ZAID

Checked by *Surjeet*
NAME: SURJEET KAUR

Name : Mrs. Swati Dhawan
Designation : QC MOD

Qualification : *Microbiology*
Approved by
NAME: MRS. SWATI DHAWAN

Patna Technical University, Jalandhar