

Title

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Certificate of Analysis Finished Product

Product Name	VANCAN Injection	A.R. No.	ARN/FP/26/004
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2606A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	28/04/2026
Mfg. Date	04/2026	Date of Testing	29/04/2026
Exp. Date	03/2028	Date of Release	14/05/2026

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.	Complies
4.	Uniformity of weight	Average weight $\pm 10\%$	-2.96 & +5.82%
5.	Average weight	Informative $\pm 2\%$.	545.2 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.81
7.	Vancomycin B	NLT 88.0%	95.58%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	1.03%
	Total impurities	NMT 12.0%	4.42%
9.	Water	NMT 5% w/w	2.79%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	148/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

Analysis by

NAME: SACHIN KUMAR

Checked by

NAME: SUFIYAN ANSARI

Approved by

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	510.5981 mg	102.12%	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/AHS.

Analysis by NAME: SACHIN KUMAR	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
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