

Title
:
Certificate of Analysis Finished Product

Product Name	VANCAN Injection	A.R. No.	ARN/FP/26/059
Generic Name	Vancomycin Hydrochloride for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN2647A	Sampled by	Rakesh
Batch Size	4830 Vials	Sampled on	27/08/2026
Mfg. Date	08/2026	Date of Testing	28/08/2026
Exp. Date	07/2028	Date of Release	11/09/2026
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 $\pm 10\%$	-3.99 & +3.74%
5.	Average weight	Informative $\pm 2\%$.	1039.6 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.88
7.	Vancomycin B	NLT 88.0%	95.640%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	1.149%
	Total impurities	NMT 12.0%	4.360%
9.	Water	NMT 5% w/w	1.88%w/w
10.	Particulate Matter		
	(A.) Light Obscuration		
	Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	1,783/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	3/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 : QCHDD

Qualification : M.V. Clinical Microbiology

Registration No. : 580406029503

Punjab Technical University, Jalandhar

Analysis by

NAME: MOHD. ZAID

Checked by

NAME: SURJEET KAUR

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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		1000 mg	1033.512 mg	103.35%	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.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 580100320103

Approved by
NAME: MRS. SWATI DHAWAN
Punjab Technical University, Jalandhar

Analysis by NAME: MOHD. ZAID	Checked by NAME: SURJEET KAUR	
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