

Title

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**Certificate of Analysis Finished Product**

Product Name	VANCAN Injection	A.R. No.	ARN/FP/26/005
Generic Name	Vancomycin Hydrochloride for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN2607A	Sampled by	Rakesh
Batch Size	15,000 Vials	Sampled on	28/04/2026
Mfg. Date	04/2026	Date of Testing	29/04/2026
Exp. Date	03/2028	Date of Release	13/05/2026

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	<b>A.</b> 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>B.</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 %	-3.95 & +5.39%
5.	Average weight	Informative $\pm$ 2%.	1119.7 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.87
7.	Vancomycin B	NLT 88.0%	95.64%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	1.03%
	Total impurities	NMT 12.0%	4.36%
9.	Water	NMT 5% w/w	2.09%w/w
10.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq$ 10 $\mu$ m (2.) Particles $\geq$ 25 $\mu$ m	NMT 6000/vial NMT 600/vial	139/vial 2/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		1000 mg	1018.684 mg	101.87%	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  NAME: SACHIN KUMAR	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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