

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	VANCAN 1000 Injection	<b>A.R. No.</b>	NB/FP/25/143
<b>Generic Name</b>	Vancomycin Hydrochloride for Injection IP 1 gm	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	N25138A	<b>Sampled by</b>	Aakash
<b>Batch Size</b>	10,176 Vials	<b>Sampled on</b>	17/07/2025
<b>Mfg. Date</b>	06/2025	<b>Date of Testing</b>	17/07/2025
<b>Exp. Date</b>	05/2027	<b>Date of Release</b>	01/08/2025

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%w/v 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 $\pm 10\%$	-7.03% & +2.99%
5.	Average weight	Informative $\pm 2\%$ .	1081.2 mg
6.	pH	2.5 to 4.5 (5%w/v solution of Vancomycin HCl).	3.14
7.	Vancomycin B	NLT 88.0%	97.63%
8.	Related substances (By HPLC)		
	Single maximum impurity	NMT 4.0%	1.46%
	Total unknown impurities	NMT 12.0%	2.32%
9.	Water	NMT 5%w/w	2.69%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	1239/vial 1/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: NIKHIL SHARMA <i>18/08/2025</i>	Checked by NAME: SUFIYAN ANSARI <i>01/08/25</i>	Approved by NAME: SWATI DHAWAN <i>01/08/25</i>
---	---	--



# Pace

Add Pace To Health

# Pace Biotech

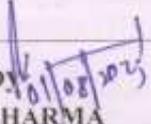
Surajpur, Paonta sahib Dist. Sirmour (H.P)

## Title : Certificate of Analysis Finished Product

Product Name	VANCAN 1000 Injection	A.R. No.	NB/FP/25/143
Generic Name	Vancomycin Hydrochloride for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	N25138A	Sampled by	Aakash
Batch Size	10,176 Vials	Sampled on	17/07/2025
Mfg. Date	06/2025	Date of Testing	17/07/2025
Exp. Date	05/2027	Date of Release	01/08/2025

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 (As sterile freeze dried powder)		1000 mg	1002.00 mg	100.20%	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 JP/BP/USP/HS.

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: SWATI DHAWAN
--	---	---

