

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/25/091
Generic Name	Vancomycin Hydrochloride for Injection IP 1000mg	Sampled qty.	45 Vials
Batch No.	N25086A	Sampled by	Rakesh
Batch Size	15,000 Vials	Sampled on	15/06/2025
Mfg. Date	06/2025	Date of Testing	16/06/2025
Exp. Date	05/2027	Date of Release	30/06/2025

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	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%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 %	-1.56% & +2.06%
5.	Average weight	Informative.	1095.2 mg
6.	pH	2.5 to 4.5 (5%w/v solution of Vancomycin HCl).	2.82
7.	Vancomycin B	NLT- 88.0%	100.0%
8.	Related substances (By HPLC)		
	Single maximum impurity	NMT- 4.0%	Not detected
	Total unknown impurities	NMT- 12.0%	Not detected
9.	Water	NMT- 5% w/w	3.27%w/w
10.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles \geq 10 μ m	NMT-6000/vial	374/vial
	(2.) Particles \geq 25 μ m	NMT-600/vial	2/vial
	(b.) Visual	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

Checked by

pace

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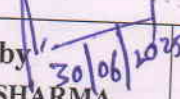
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11.	Sterility	No microbial growth should be observed.	Complies		
12.	Bacterial Endotoxins	NMT 2.5 EU/ml of Vancomycin.	Less than 2.5 EU/ml of Vancomycin.		
13.	Assay: (By Microbiology) Each glass vial Contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Vancomycin Hydrochloride (Sterile) IP Eq. to Vancomycin. (As sterile freeze dried powder)		1000 mg	993.819 mg	99.38%	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: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: SWATI DHAWAN
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