

Pace

Add Pace To Health

Pace Biotech

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

Certificate of Analysis Finished Product

Title	:		
Product Name	VANCAN 1000 Injection	A.R. No.	NB/FP/24/256
Generic Name	Vancomycin Hydrochloride for Injection IP 1000mg	Sampled qty.	45 Vials
Batch No.	N24216A	Sampled by	Boby Kumar
Batch Size	8000 Vials	Sampled on	28/11/2024
Mfg. Date	10/2024	Date of Testing	28/11/2024
Exp. Date	09/2026	Date of Release	13/12/2024

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
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 %	-2.47% & +3.62%
5.	Average weight	Informative.	1122.9 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin HCl).	2.89
7.	Vancomycin B	Should be complies.	Complies
8.	Related substances (By HPLC)		
	Any impurity	NMT- 4.0%	Complies
	Total impurity	NMT- 12.0%	Complies
9.	Water	NMT- 5% w/w	2.06%w/w
10.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles \geq 10 μ m	NMT-6000/vial	1050/vial
	(2.) Particles \geq 25 μ m	NMT-600/vial	7/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
NAME: SUFIYAN ANSARI

Checked by
NAME: SANDHYA

Approved by
NAME: DIVYA SHARMA



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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) Eq. to Vancomycin		1000 mg	1014.457 mg	101.45%	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/HHS.

Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: DIVYA SHARMA <i>Manager</i>
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