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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/24/321
Generic Name	Vancomycin Hydrochloride for Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	N24312B	**Sampled by**	Rakesh
Batch Size	4000 Vials	**Sampled on**	20/01/2025
Mfg. Date	01/2025	**Date of Testing**	20/01/2025
Exp. Date	12/2026	**Date of Release**	05/02/2025

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 ± 10%	-7.35% & +5.44%
5.	Average weight	Informative.	1095.9 mg
6.	pH	2.5 to 4.5 (5%w/v solution of Vancomycin HCl).	2.74
7.	Vancomycin B	NLT- 88.0%	97.61%
8.	Related substances (By HPLC)		
	Any impurity	NMT- 4.0%	0.53%
	Sum of all impurities	NMT- 12.0%	2.39%
9.	Water	NMT- 5% w/w	3.11%w/w
10.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	NMT-6000/vial NMT-600/vial	343/vial 3/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

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager

Analysis by	Checked by	Approved by

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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.	997.96 mg	99.80%	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/IHS~~.

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager

Analysis by	Checked by	Approved by
NAME: SUFIYAN ANSARI	NAME: SANDHYA	NAME: B.N. TRIPATHI