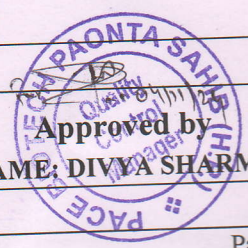


Certificate of Analysis Finished Product

Title	:		
Product Name	VANCAN 1000 Injection	A.R. No.	NB/FP/24/204
Generic Name	Vancomycin Hydrochloride for Injection IP 1000mg	Sampled qty.	45 Vials
Batch No.	N24202B	Sampled by	Boby Kumar
Batch Size	2000 Vials	Sampled on	16/10/2024
Mfg. Date	10/2024	Date of Testing	16/10/2024
Exp. Date	09/2026	Date of Release	04/11/2024

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 %	-3.68% & +4.08%
5.	Average weight	Informative.	1099.4 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin HCl).	2.68
7.	Vancomycin B	Should be complies.	Complies
8.	Related substances (By HPLC)		
	Any impurity	NMT- 4.0%	Not detected
	Total impurity	NMT- 12.0%	Not detected
9.	Water	NMT- 5% w/w	2.25%w/w
10.	Particulate Matter		
	(a.) Sub-Visible particle count	NMT-6000/vial	167/vial
	(1.) Particles \geq 10 μ m	NMT-600/vial	1/vial
	(2.) Particles \geq 25 μ m		Complies
	(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.	

Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: NEHA	Approved by NAME: DIVYA SHARMA
-------------------------------------	--------------------------	-----------------------------------



Title

:

Certificate of Analysis Finished Product

Product Name	VANCAN 1000 Injection	A.R. No.	NB/FP/24/204
Generic Name	Vancomycin Hydrochloride for Injection IP 1000mg	Sampled qty.	45 Vials
Batch No.	N24202B	Sampled by	Boby Kumar
Batch Size	2000 Vials	Sampled on	16/10/2024
Mfg. Date	10/2024	Date of Testing	16/10/2024
Exp. Date	09/2026	Date of Release	04/11/2024

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	1008.317 mg	100.83%	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.

Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: NEHA	Approved by NAME: DIVYA SHARMA
-------------------------------------	--------------------------	-----------------------------------

