



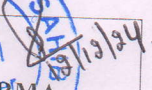
Title

Certificate of Analysis Finished Product

Product Name	VANCAN Injection	A.R. No.	NB/FP/24/253
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	N24223H	Sampled by	Boby Kumar
Batch Size	5040 Vials	Sampled on	26/11/2024
Mfg. Date	11/2024	Date of Testing	26/11/2024
Exp. Date	10/2026	Date of Release	12/12/2024

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) IP Eq. to Vancomycin		500 mg	485.749 mg	97.15%	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/HS.

Analysis by  NAME: SUFIYAN ANSARI	Checked by  NAME: SANDHYA	Approved by  NAME: DIVYA SHARMA
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Title

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
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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	<p>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.</p> <p>B. It gives reaction (A) of chloride.</p>	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 %	-0.95% & +0.71%
5.	Average weight	Informative.	547.1 mg
6.	pH	2.5 to 4.5(5% w/v solution of Vancomycin Hcl).	2.84
7.	Vancomycin B	Should be complies.	Complies
8.	Related substances		
	Any impurity	NMT- 4.0%	Complies
	Sum of any such impurities	NMT- 12.0%	Complies
9.	Water	NMT- 5% w/v	2.30%w/w
10.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles \geq 10 μ m	NMT-6000/vial	1014/vial
	(2.) Particles \geq 25 μ m	NMT-600/vial	10/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

