Nixi Laboratories Pvt. Ltd.

VPO: Mouza Ogli, Sadhora Road, Kala Amb Distt. Sirmour (H.P)

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	VANCAN-500	**AR. No.**	NL/DI/FG/23/689
Generic Name	Vancomycin Hydrochloride For Intravenous Infusion IP		
Mother Batch No.	D23AK006	**Reference**	IP
Child Batch No.	D23AK007A	**Batch size**	10200Vials
Mfg. Date	11/2023	**Exp. Date**	10/2025
Specification No. (STS No.)	QC/DPI/FG/STS/023-01	**Standard Test Procedure No.**	QC/DPI/FG/STP/023
Sampled Quantity	25 Vials	**Sampling Date**	26/10/2023
Released Date	09/11/2023		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	White or off white powder filled in 10 ml clear glass vial, plugged with grey rubber stopper and sealed with flip off aluminium seal.	White powder filled in 10 ml clear glass vial, plugged with grey rubber stopper and sealed with flip off aluminum seal.
2.	Identification: A. By HPLC B. By Chemical (Chloride)	In the test for Vancomycin B, the retention time of the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained of with the reference solution. A curdy white precipitate is formed.	Complies Complies
3.	Appearance of solution	Vancomycin is clear. The absorption of the solution at 450 nm is not more than 0.1	Complies 0.066
4.	Constitutes of solution	The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injections contained in a similar container and examined in the same manner. The reconstitutes time is 180 seconds maximum.	Complies
5.	Average filled Weight	525 mg ± 5.0%	525.6 mg
6.	Uniformity of filled weight	Fill weight ± 5.0%	-2.73% to +2.07%
7.	pH	2.5 to 4.5	3.56
8.	Particulate matter		

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	**Aradhana Tiwari**	**Happy Saini**	**Aditya Singh**
Signature			
Date	09/11/2023	09/11/2023	09/11/23

Nixi Laboratories Pvt. Ltd. QC APPROVED Mouza Ogli Kala-Amb (H.P.)

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	For Visible Particles	Should be free from visible particles	Complies
	For sub visible particles: (i) Equal to or greater than 10µm (ii) Equal to or greater than 25µm	NMT 6000 particle/container NMT600 particle/container	96.0 particle/container 03.0 particle/container
9.	Sterility	Should comply the test of sterility	Complies
10.	Bacterial Endotoxins	NMT 2.5 EU/ml of Vancomycin	Complies
11.	Water Content	Not more than 5.0%	2.20%
12.	Vancomycin B	Not less than 88.0 %	95.09%
13.	Related Substances		
	A. Any Impurity B. Total Impurity	NMT 4.0% NMT 12.0%	0.99% 4.90%
14.	Assay		
	Each vial contains : Vancomycin Hydrochloride IP Eq. to Vancomycin 500mg	450.00 mg to 550.00 mg (90.00% to 110.00%)	504.05 mg/vial 100.81%

Result: The above sample **COMPLIES/~~DOES NOT COMPLY~~** as per Specification No- QC/DPI/FG/STS/023-01. **Conclusion:** In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS ~~NOT STANDARD QUALITY~~** as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	**Aradhana Tiwari**	**Happy Saini**	**Aditya Singh**
Signature			
Date	09/11/2023	09/11/2023	09/11/23

Nixi Laboratories Pvt. Ltd. QC APPROVED Mouza Ogli Kala-Amb (H.P.)