Nixi Laboratories Pvt. Ltd.

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

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	TEICOCAN-200	**AR. No.**	NL/DI/FG/24/746
Generic Name	Teicoplanin for Injection IP		
Mother Batch No.	D24AX004	**Reference**	IP/IHS
Child Batch No.	D24AX004D	**Batch Size**	500 Vials
Mfg. Date	08/2024	**Exp. Date**	07/2026
Specification No. (STS No)	QC/DPI/FG/STS/011-01	**Standard Test Procedure No.**	QC/DPI/FG/STP/011
Sample Quantity	45 Vials	**Sampled Date**	13/08/2024
Released Date	28/08/2024		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	**Description**	White or off white to yellowish powder filled in 10 ml clear glass vial, plugged with rubber stopper and sealed with flip off aluminum seal.	White to Yellowish powder filled in 10 ml clear glass vial, plugged with rubber stopper and sealed with flip off aluminum seal.
2.	**Identification:** **(A) By UV-visible Spectrophotometer** **(B) By High Performance Liquid Chromatography (HPLC)**	It shows an absorption maximum at about 278 nm. In composition and related substances obtained the principal peaks (Teicoplanins A_{3-1}, A_{2-1}, A_{2-2}, A_{2-3}, A_{2-4}, and A_{2-5}) in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the reference solution.	Complies Complies
3.	**Clarity of solution**	a) The solid dissolves completely, leaving no visible residue as undissolved matter. b) 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	Complies Complies
4.	**Average filled weight**	210 mg ± 5%	207.1 mg
5.	**Uniformity of weight**	Average filled weight ± 5.0%	-1.4%, + 1.3%

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	**Tarun Kumar**	**Ganesh Jaiswal**	**Aditya Singh**
Signature			
Date	28/08/24	29/08/24	28/08/24

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

	Nixi Laboratories Pvt. Ltd. **VPO: Mouza Ogli, Sadhora Road, Kala Amb Distt. Sirmour (H.P)**

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

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6.	**pH**	6.0 to 8.0	7.01
7.	**Particulate matter**		
	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 particles/container NMT 600 particles/container	287.0 particles/container 7.0 particles/container
8.	**Sterility**	Should comply the test of sterility	Complies
9.	**Bacterial Endotoxins**	NMT 0.30 EU/mg of Teicoplanin	Complies
10.	**Water content**	NMT 5.0 %	2.68 %
11.	**Composition & Related substances**		
	(i) Teicoplanin A_2 group (ii) Teicoplanin A_3 group (iii) Sum of all other Secondary impurity	NLT 75 % NMT 20 % NMT 5.0 %	82.90% 15.58% 1.52%
12.	**Assay:**		
	Each Vial contains: Teicoplanin IP 200 mg	180.00 mg to 240.00 mg (90.00 % To 120.00 %)	201.34 mg (100.67%)

RESULT: The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No- QC/DPI/FG/STS/011-01.

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 here under further

	ANALYSED BY	**CHECKED BY**	**APPROVED BY**
Name	**Tarun Kumar**	**Ganesh Jaiswal**	**Aditya Singh**
Signature			
Date	28/08/24	28/08/24	28/08/24

Nixi Laboratories Pvt. Ltd. QC APPROVED Mouza Ogli Kala-Amb