



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/24/850
Generic Name	Teicoplanin Injection IP		
Mother Batch No.	D24AX005	Reference	IP/IHS
Child Batch No.	D24AX005B	Batch Size	600 Vials
Mfg. Date	09/2024	Exp. Date	08/2026
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	24/09/2024
Released Date	08/10/2024		

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 aluminium seal.	Off 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	203.83 mg ± 5%	204.9 mg
5.	Uniformity of weight	Average filled weight ± 5.0%	-2.80%, + 1.20%

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Signature			
Date	08/10/24	08/10/24	08/10/24





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6.	pH	6.0 to 8.0	7.05
7.	Particulate matter		
	For Visible Particles:	Should be free from visible particles	Complies
	For sub visible particles		
	(i) Equal to or greater than 10µm	NMT 6000 particles/container	1408.7 particles/container
	(ii) Equal to or greater than 25µm	NMT 600 particles/container	37.3 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 %	2.13%
11.	Composition & Related substances		
	(i) Teicoplanin A ₂ group	NLT 75 %	81.59%
	(ii) Teicoplanin A ₃ group	NMT 20 %	14.97%
	(iii) Sum of all other Secondary impurity	NMT 5.0 %	3.44%
12.	Assay:		
	Each Vial contains: Teicoplanin IP 200 mg	180.00 mg to 240.00 mg (90.00 % To 120.00 %)	203.28 mg (101.64%)

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	08/10/24	08/10/24	08/10/24

