



Nixi Laboratories Pvt. Ltd.,
Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030,
Himachal Pradesh (INDIA).

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	TEICOCAN 400	AR. No.	NL/DI/FG/26/088
Generic Name	Teicoplanin Injection IP 400mg		
Mother Batch No.	D26AY001	Reference	IP
Child Batch No.	D26AY001F	Batch Size	950 Vials
Mfg. Date	01/2026	Exp. Date	12/2027
Specification No. (STS No)	QC/DPI/FG/STS/011-02	Standard Test Procedure No.	QC/DPI/FG/STP/011
Sample Quantity	70 Vials	Sampled Date	19/01/2026
Released Date	02/02/2026		

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.	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 manner.	Complies Complies
4.	Average filled weight	filled weight \pm 5%	399.56 mg

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Rahul Singh	Ganesh Jaiswal	Aditya Singh
Designation	Sr. Officer QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	02/02/26	02/02/26	02/02/26

Format No.: F/QC/013/03-04

Approved By Page 1 of 2
Name: Aditya Singh
Designation: Asst. Manager QC
Qualification: Bsc
Enrollment No. II-009545
Avadh University Ayodhya



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Sr.No.	TEST	SPECIFICATION	OBSERVATION
5.	Uniformity of weight	Average filled weight \pm 5%	-1.32% +2.24%
6.	pH	6.0 to 8.0	7.20
7.	Particulate matter		
	For Visible Particles:	Should be free from visible particles	Complies
	For sub visible particles (i) Equal to or greater than 10 μ m (ii) Equal to or greater than 25 μ m	NMT 6000 particles/container NMT 600 particles/container	969.0 particles/container 19.0 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 %	2.0%
11.	Composition & Related substances		
	(i) Teicoplanin A ₂ group (ii) Teicoplanin A ₃ group (iii) Sum of all other Secondary impurity	NLT 75.0 % NMT 20.0 % NMT 5.0 %	80.57% 15.96% 3.47%
12.	Assay:		
	Each Vial contains: Teicoplanin IP 400 mg	360.00 mg to 480.00 mg (90.00 % To 120.00 %)	403.80 mg (100.95%)

RESULT:The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No- QC/DPI/FG/STS/011-02.

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	Rahul Singh	Ganesh Jaiswal	Aditya Singh
Designation	Sr.Officer QC	Sr.Executive QC	Asst.Manager QC
Signature			
Date	02/02/26	02/02/26	02/02/26