

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Tigican 50 mg injection (Tigecycline Injection IP 50mg)		
Batch No.	26LVG029D	A.R. No.	FP260340
Batch Size	2010 Vials	Sample Quantity	60 NOS
Mfg. Date	07/2026	Date of Testing	25/07/2026
Exp. Date	06/2028	Date of Release	10/08/2026
Reference Batch No	26LVG029	MFG. Lic. No.	N-MB/2023/263

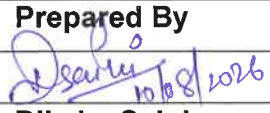
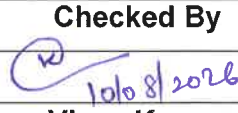
Sr. No.	Test	Specification	Observation
1.	Description	An orange colour Lyphilized	An orange colour Lyphilized
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with working standard	Complies
3.	Related Substance A.) Tigecycline open ring B.) Tigecycline 12-oxo-11-hydroxy C.) Tigecycline tricycline D.) Tigecycline Quinine E.) Tigecycline impurity B F.) Tigecycline Epimer G.) Any other impurity H.) Total impurity	NMT (0.15 per cent) NMT (0.5 per cent) NMT (0.5 per cent) NMT (0.3 per cent) NMT (0.7 per cent) NMT (2.0 per cent) NMT (0.2 per cent) NMT (6.0 per cent)	Complies
4.	pH	4.5 to 5.5	5.28
5.	Bacterial Endotoxins	NMT 1.75 EU/mg	Less than 1.75 EU/mg

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6.	Sterility	Should be Sterile	Sterile
7.	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 injection contained in a similar container and examined in the same manner.	Complies
8.	Particulate matter	Constitute the injection in a water for injection; the solution is essentially free from particles of foreign matter that can be seen on visual inspection	Complies
9.	Assay:	96.0 to 116.0% (48.0 to 58.0 mg)	102.31 % (51.15 mg)

Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date			
Name	Diksha Saini	Vinay Kumar	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC