

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Tigican injection (Tigecycline Injection IP 50mg)		
Batch No.	26LVC007E	A.R. No.	FP260135
Batch Size	2000 Vials	Sample Quantity	60 NOS
Mfg. Date	03/2026	Date of Testing	24/03/2026
Exp. Date	02/2028	Date of Release	08/04/2026
Reference Batch No	26LVC007	MFG. Lic. No.	N-MB/2023/263

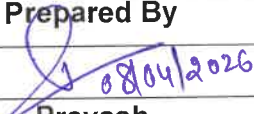
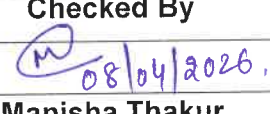
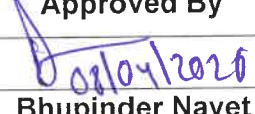
Sr. No.	Test	Specification	Observation
1.	Description	An orange colour Lyphilized Cake	An orange colour Lyphilized Cake
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with working standard	Complies
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	4.60
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	<p>A) The solid dissolves completely, leaving no visible residue as undissolved matter.</p> <p>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.</p>	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: Assay: Each Vial contains Tigecycline IP 50 mg	96.0 to 116.0% (48.0 to 58.0 mg)	100.38 % (50.19 mg)

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

	Prepared By	Checked By	Approved By
Sign/Date	 08/04/2026	 08/04/2026	 08/04/2026
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC