PACEBIOTECH PHARMA (INDIA) PVT. LTD.

PacebiotechPharma (India) Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	**TIGICAN 50 Injection (Tigecycline for Injection IP 50 mg)**		
Batch No.	26LVI036F	**A.R. No.**	FP260415
Batch Size	1040 Vials	**Sample Quantity**	60 Vials
Mfg. Date	09/2026	**Date of Testing**	08/09/2026
Exp. Date	08/2028	**Date of Release**	23/09/2026
Reference Batch No	26LVI036	**MFG. Lic. No.**	N-MB/2023/263

Sr. No.	Test	Specification	Observation
1.	**Description**	Orange colour lyophilized cake filled in clear colourless vial	Orange colour lyophilized cake filled in clear colourless vial
2.	**Identification (By HPLC)**	In the assay, The principal peaks in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the reference solution.	Complies
3.	**pH**	4.5 to 5.5	4.68
4.	**Bacterial Endotoxins**	NMT 1.75 EU/mg	Less than 1.75 EU/mg
5.	**Sterility**	Should be Sterile	Sterile
6.	**Related Substance** **Tigecycline open ring** **Tigecycline 12-oxo-11-hydroxy** **Tigecycline tricycline** **Tigecycline Quinine** **Tigecycline impurity B** **Tigecycline Epimer** **Any other impurity** **Total impurity**	 NMT 0.15% NMT 0.5% NMT 0.5% NMT 0.3% NMT 0.7% NMT 2.0% NMT 0.2% NMT 6.0%	 Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected
7.	**Uniformity of Weight**	190 mg ± 10%	192.04 mg
8.	**Clarity of solution**	A) The solid dissolves completely, leaving no visible residue as undissolved matter.	Complies

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	**TIGICAN 50 Injection (Tigecycline for Injection IP 50 mg)**		
Batch No.	26LVI036F	**A.R. No.**	FP260415
Batch Size	1040 Vials	**Sample Quantity**	60 Vials
Mfg. Date	09/2026	**Date of Testing**	08/09/2026
Exp. Date	08/2028	**Date of Release**	23/09/2026
Reference Batch No	26LVI036	**MFG. Lic. No.**	N-MB/2023/263

		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
9.	**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
10.	**Assay:** **Each Vial Contains:** **Tigecycline (Sterile) IP 50 mg**	48.0 to 58.0 mg (96.0 to 116.0%)	50.50 mg 101.01%

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

	Prepared By	Checked By	Approved By
Sign/Date	23/09/2026	23/09/2026	23/09/2026
Name	**Diksha Saini**	**Vinay Kumar**	**Bhupinder Navet**
Designation	**Officer QC**	**Sr.Executive-QC**	**Head-QC**

Name: Bhupinder Navet
Designation: Head QC
Qualification: M. Pharma
Registration No: 12-DVI-103
Pt BD Sharma University of Health Sciences, Rohtak