

**QUALITY CONTROL  
CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)**

<b>Format No.:</b> KBPL/QC/030/F03-01			
<b>Product Name</b>	TIGICAN 50 Injection		
<b>Generic Name</b>	Tigecycline for Injection USP 50 mg/vial		
<b>Batch No.</b>	K09524002	<b>A.R. No.</b>	FP/04/24/00022
<b>Mfg. Date</b>	Apr-2024	<b>Sampling Quantity</b>	80 vials
<b>Exp. Date</b>	Mar-2026	<b>Sampling Date</b>	22/04/2024
<b>Batch Size</b>	17000 vials	<b>Date of Analysis</b>	22/04/2024
<b>Pack Quantity</b>	NA	<b>Date of Release</b>	06/05/2024
<b>Ref. Spec. No.</b>	SPC/FG00000095-00	<b>Page No.</b>	Page 1 of 2
<b>Pack Size/Type</b>	1 Vial		

Sr. No.	Test	Specification	Result
01	<b>Description</b>	Orange colour cake or powder	Orange colour cake
02	<b>Identification</b>		
2.1	(By HPLC)	The retention time of major peak of the sample solution corresponds to that of standard solution as obtained in the test assay.	Complies
2.2	(By UV)	The UV spectrum of the major peak of the sample solution corresponds to that of standard solution as obtained in the test assay.	Complies
03	<b>pH</b>	Between 4.5 to 5.5	5.2
04	<b>Clarity and Colour of Solution</b>		
		The solid dissolves completely, leaving no visible residue as undissolved matter. 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
05	<b>Assay (By HPLC)</b>	Not less than 96.0 % and not more than 116.0 % of labeled amount of Tigecycline.	101.8 %
06	<b>Organic Impurities (By HPLC)</b>		
6.1	Tigecycline Open Ring	Not more than 0.15%	Not Detected
6.2	Tigecycline 12-oxo-11-hydroxy	Not more than 0.5%	Not Detected
6.3	Tigecycline Related Compound B	Not more than 0.7%	Not Detected
6.4	Tigecycline epimer	Not more than 2.0%	Not Detected



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Sr. No.	Test	Specification	Result
6.5	Tigecycline quinone analog	Not more than 0.3%	Not Detected
6.6	Tigecycline tricyclic analog	Not more than 0.5%	Not Detected
6.7	Any individual unspecified degradation product	Not more than 0.2%	0.10 %
6.8	Total degradation products	Not more than 6.0%	0.10 %
07	<b>Bacterial Endotoxins</b>	NMT 1.75 USP EU/mg	Less than 1.75 USP EU/mg
08	<b>Uniformity of Dosage Unit</b>	Only for information	132.6 mg
09	<b>Particulate Matter</b>		
	≥10µm	NMT 6000 no. of particles per container.	265 particles per container
	≥ 25µm	NMT 600 no. of particles per container	1 particle per container
10	<b>Sterility</b>	Should be sterile.	Sterile

**CONCLUSION:** The Finish Product Sample Complies / ~~Does not complies~~ as per IP/HP/USP Specification.

Function	Prepared By	Reviewed By	Approved By
Name	Maya Sirsat	Kushal Deshmukh	Avnish Kumar
Designation-Department	Executive-QC	Asst. Manager-QC	Manager-QC
Sign & Date	 12/05/2024	 12/05/2024	 12/05/2024

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