



Nixi Laboratories Pvt. Ltd.
VPO: Mouza Ogli, Sadhora Road, Kala Amb Distt. Sirmour (H.P)

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	Tigican- 50	AR. No.	NL/LYP/FG/24/192
Generic Name	Tigecycline Injection IP 50 mg/vial		
Mother Batch No.	L24DT010	Reference	IP
Child Batch No.	L24DT010G	Batch Size	500 Vials
Mfg. Date	07/2024	Exp. Date	06/2026
Specification No.	QC/LYP/FG/STS/014-01	Standard Test Procedure No.	QC/LYP/FG/STP/014
Quantity Sampled	45 Vials	Sampling Date	24/07/2024
Release Date	21/08/2024		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	An orange color cake filled in 10 ml tubular clear glass vial, plugged with grey rubber stopper and sealed with flip of aluminum seal.	Orange color cake filled in 10 ml tubular clear glass vial, plugged with grey rubber stopper and sealed with flip of aluminum seal.
2.	Identification: (A) By High Performance Liquid Chromatography (HPLC)	In the Assay, Principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a).	Complies
3.	Constituted solution: Completeness and clarity of solutions	<ul style="list-style-type: none">The solid dissolves completely, leaving no undissolved matter.The constituted solution is not significantly less clear than an equal volume of the diluent or of purified water contained in a similar vessel and examined similarly. Protein solutions may exhibit an inherent opalescence.The constituted solution is free from particulate matter that can be observed on	Complies Complies Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Signature			
Date	21/08/24	21/08/24	21/08/24





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		visual inspection	
4.	Average filled Weight	185 mg \pm 10%	174.93 mg
5.	Uniformity of filled Weight	Average filled weight \pm 10%	-8.7% +8.0%
6.	pH (25°C\pm2 °C)	4.50 to 5.50	5.14
7.	Particulate matter		
	Visible Particles:	Should be free from visible particles	Complies
	For sub visible particles: Equal to or greater than 10 μ m Equal to or greater than 25 μ m	NMT 6000 particles/container NMT 600 particles/container	717.0 particles/Container 23.0 particles/Container
8.	Sterility	Should be complies	Complies
9.	Bacterial Endotoxins	Not more than 1.75 EU /mg of	Complies

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		Tigecycline	
10. Related Substances (By HPLC)			
(i) Tigecycline open ring ^{1,2}	Not more than 0.15%	Not Detected	
(ii) Tigecycline 12-oxo-11-hydroxy ³	Not more than 0.5%	Not Detected	
(iii) Tigecycline related compound B ⁴	Not more than 0.7%	Not Detected	
(iv) Tigecycline epimer ⁵	Not more than 2.0%	Not Detected	
(v) Tigecycline quinone analog ⁶	Not more than 0.3%	Not Detected	
(vi) Tigecycline tricyclic analog ⁷	Not more than 0.5%	Not Detected	
(vii) Any other secondary peak	Not more than 0.2%	Not Detected	
(viii) All the secondary peak	Not more than 6.0%	Not Detected	
11. Assay: Each Lyophilized vial contains: Tigecycline IP 50 mg	48.00 mg to 58.00 mg (96.0% to 116.0%)	50.42 mg (100.84 %)	

Result: The above sample **COMPLIES / DOES NOT COMPLY** as per Specification No-QC/LYP/FG/STS/014-01.

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 hereunder further.

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Date	21/08/24	21/08/24	21/08/24

