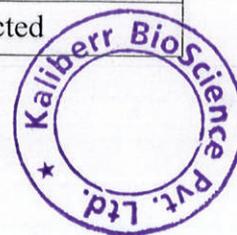


**QUALITY CONTROL
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Format No.: KBPL/QC/030/F03-01			
Product Name	DOXYCIN 100 Injection		
Generic Name	Doxycycline for Injection USP 100 mg/vial		
Batch No.	K10624007	A.R. No.	FP/09/24/00025
Mfg. Date	Sep-2024	Sampling Quantity	60 vials
Exp. Date	Aug-2026	Sampling Date	16/09/2024
Batch Size	5.0 Kg X 2 Lot	Date of Analysis	16/09/2024
Pack Quantity	NA	Date of Release	30/09/2024
Ref. Spec. No.	FP/SPC/0067-00	Page No.	Page 1 of 2
Pack Size/Type	1 Combipack		

Sr. No.	Test	Specification	Result
01	Description	A Yellow powder.	A Yellow powder.
02	Identification		
A.	By UV	The UV spectrum of the major peak of the sample solution corresponds to that of standard solution.	Complies
B.	By HPLC	The retention time of major peak of the sample solution corresponds to that of standard solution.	Complies
03	pH	Between 1.8 to 3.3	2.4
04	Loss on Drying	NMT 4.0% for the article containing no added substances	0.7 %
05	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container.	306 per container
	≥ 25 µm	NMT 600 no. of particles per container.	10 per container
06	Constituted Solution	The solution is not less clear than an equal volume of the same solvent.	Complies
07	Uniformity of Weight	As per current BMR	114.6 mg
08	Organic Impurities (By HPLC)		
8.1	4-Epidoxycycline	NMT 2.2%	Not Detected
8.2	Any individual unspecified impurity	NMT 0.5%	Not Detected
8.3	Total Impurities	Not more than 5.5%	Not Detected

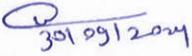


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09	Sterility	Should be sterile	Sterile
10	Bacterial Endotoxins	NMT 1.14 USP EU/mg of Doxycycline	Less than 1.14 USP EU/mg
11	Assay (By HPLC)	Not less than 90.0% and not more than 120.0% of labeled amount of Doxycycline.	98.5 %

CONCLUSION: The Finish Product Sample Complies / Does not complies as per IH/IP/BP/USP Specification.

Function	Prepared By	Reviewed By	Approved By
Name	Ujwala Chaudhari	Maya Sirsat	Avnish Kumar
Designation-Department	Officer - QC	Executive - QC	Manager-QC
Sign & Date	 30/09/2024	 30/09/2024	 30/09/2024

Kaliberr BioScience Pvt. Ltd.

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