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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	Maya 30/09/2024	30/09/2024

Kaliberr BioScience Pvt. Ltd.

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