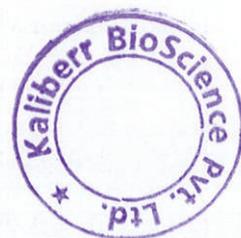


Format No.: KBPL/QC/030/F03-01

<b>Product Name</b>	<b>Doxycin 100</b>		
<b>Generic Name</b>	<b>Doxycycline for Injection USP 100 mg/vial</b>		
<b>Batch No.</b>	K10624009	<b>A.R. No.</b>	FP/10/24/00013
<b>Mfg. Date</b>	Sep - 2024	<b>Sampling Quantity</b>	60 vials
<b>Exp. Date</b>	Aug - 2026	<b>Sampling Date</b>	09/10/2024
<b>Batch Size</b>	5.0 Kg × 3 Lot	<b>Date of Analysis</b>	09/10/2024
<b>Pack Quantity</b>	NA	<b>Date of Release</b>	23/10/2024
<b>Ref. Spec. No.</b>	FP/SPC/0067-00	<b>Page No.</b>	Page 1 of 2
<b>Pack Size/Type</b>	1 Combi pack		

Sr. No.	Test	Specification	Result
01	<b>Description</b>	A Yellow powder.	A Yellow powder.
02	<b>Identification</b>		
A.	<b>By UV</b>	The UV spectrum of the major peak of the sample solution corresponds to that of standard solution.	Complies
B.	<b>By HPLC</b>	The retention time of major peak of the sample solution corresponds to that of standard solution.	Complies
03	<b>pH</b>	Between 1.8 to 3.3	2.6
04	<b>Loss on Drying</b>	NMT 4.0% for the article containing no added substances	0.74 %
05	<b>Particulate Matter</b>		
	≥ 10 µm	NMT 6000 no. of particles per container.	306 particles per container
	≥ 25 µm	NMT 600 no. of particles per container.	10 particles per container
06	<b>Constituted Solution</b>	The solution is not less clear than an equal volume of the same solvent.	Complies
07	<b>Uniformity of Weight</b>	As per current BMR	116.4 mg
08	<b>Organic Impurities (By HPLC)</b>		
8.1	<b>4-Epidoxycycline</b>	NMT 2.2%	Not Detected
8.2	<b>Any individual unspecified impurity</b>	NMT 0.5%	Not Detected
8.3	<b>Total Impurities</b>	Not more than 5.5%	Not Detected



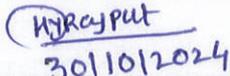
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QUALITY CONTROL  
CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	Doxycin 100		
Generic Name	Doxycycline for Injection USP 100 mg/vial		
Batch No.	K10624009	A.R. No.	FP/10/24/00013
Mfg. Date	Sep - 2024	Sampling Quantity	60 vials
Exp. Date	Aug - 2026	Sampling Date	09/10/2024
Batch Size	5.0 Kg × 3 Lot	Date of Analysis	09/10/2024
Pack Quantity	NA	Date of Release	23/10/2024
Ref. Spec. No.	FP/SPC/0067-00	Page No.	Page 2 of 2
Pack Size/Type	1 Combi pack		

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.	99.8 %

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

Function	Prepared By	Reviewed By	Approved By
Name	Harshali Rajput	Kushal Deshmukh	Avnish Kumar
Designation-Department	Officer – QC	Asst. Manager - QC	Manager - QC
Sign & Date	 30/10/2024	 30/10/2024	 30/10/2024

Kaliberr BioScience Pvt. Ltd.

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