

Format No.: KBPL/QC/030/F03-01			
Product Name	DOXYCIN 100 Injection		
Generic Name	Doxycycline for Injection USP 100 mg/vial		
Batch No.	K10624005	A.R. No.	FP/06/24/00005
Mfg. Date	Jun-2024	Sampling Quantity	60 vials
Exp. Date	May-2026	Sampling Date	03/06/2024
Batch Size	5.0 Kg X 3 Lot	Date of Analysis	03/06/2024
Pack Quantity	NA	Date of Release	17/06/2024
Ref. Spec. No.	FP/SPC/0067-00	Page No.	Page 1 of 2
Pack Size/Type	1 Combipack		


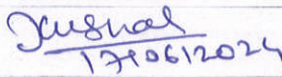
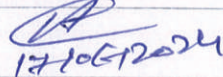
Sr. No.	Test	Specification	Result
01	Description	A Yellow powder.	A Yellow powder.
02	Identification		
A.	By UV	The UV spectrum of the major peak of the sample solution corresponds to that of standard solution.	Complies
B.	By HPLC	The retention time of major peak of the sample solution corresponds to 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	1.2 %
05	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container.	335 particles per container.
	≥ 25 µm	NMT 600 no. of particles per container.	3 particule 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	112.3 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.	100.3 %

CONCLUSION: The Finish Product Sample Complies / ~~Does not complies~~ as per IH/IP/BP/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	 17/06/2024	 17/06/2024	 17/06/2024

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