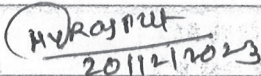
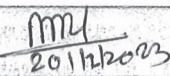
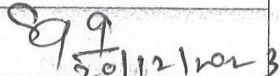


CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-00			
Product Name		COLISTICAN 3	
Generic Name		Colistimethate Sodium for Injection IP 3 MIU per Vial	
Batch No.	K03223004	A.R. No.	FP/10/23/00107
Mfg. Date	Oct-2023	Sampling Quantity	80 Vials
Exp. Date	Sep - 2025	Sampling Date	19/10/2023
Batch Size	2 Kg	Date of Analysis	19/10/2023
Pack Size/Type	1 X 10 ml Vial	Date of Release	03/11/2023
Ref. Spec. No.	SPC/FG00000032-00	Page No.	Page 1 of 3

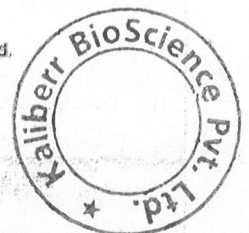
Sr. No.	Test	Specification	Result
01	Description	A white or almost white, hygroscopic powder.	A white hygroscopic powder.
02	Identification		
A)	By TLC	The spot in the chromatogram obtained with the test solution corresponds to those in the chromatogram obtained with the reference solutions (a) and (b), but shows no spots corresponding to those in the chromatogram obtained with the reference solutions (c) and (d).	Complies
B)	By Chemical Method	A purple colour should produce	Complies
C)	By Chemical Method (Sulphate)	The solution should decolorized and white precipitate is formed	Complies.
D)	By Chemical Method (Sodium Salts)	No precipitate is formed.	Complies
03	pH	Between 6.5 to 8.5	7.2

Function	Prepared By	Reviewed By	Approved By
Name	Harshali Rajput	Mayur D. Suryawanshi	Siddharth Singh
Designation-Department	Officer -QC	Officer-Micro	Sr. Executive-QC
Sign & Date	 20/11/2023	 20/11/2023	 20/11/2023

Kaliberr BioScience Pvt. Ltd.

Registered Office
Survey No. 12/1, Plot No. 23,
Tipre Colony, Camp Road, Malegaon
Dist.: Nashik, Pin Code: 423203
Maharashtra, India

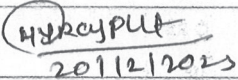
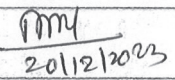
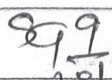
Plant Address:
Survey No. 444/1, Koshimba Road,
Khadki, Lakhmapur, Tal: Dindori,
Dist.: Nashik, Pin Code: 422202
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CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-00			
Product Name	COLISTICAN 3		
Generic Name	Colistimethate Sodium for Injection IP 3 MIU per Vial		
Batch No.	K03223004	A.R. No.	FP/10/23/00107
Mfg. Date	Oct-2023	Sampling Quantity	80 Vials
Exp. Date	Sep - 2025	Sampling Date	19/10/2023
Batch Size	2 Kg	Date of Analysis	19/10/2023
Pack Size/Type	1 X 10 ml Vial	Date of Release	03/11/2023
Ref. Spec. No.	SPC/FG00000032-00	Page No.	Page 2 of 3

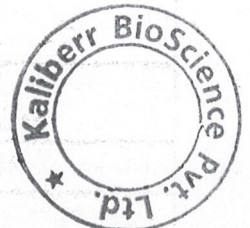
Sr. No.	Test	Specification	Result
04	Clarity and Colour of Solution		
		The Solid dissolves completely, leaving no visible residue as undissolved matter. The constituted injection is not significantly less clear than an equal volume of the diluent or of water for Injections contained in a similar container and examined in the same manner.	Complies
05	Free Colistin	The solution is not more opalescent than opalescence standard OS2.	Complies
06	Loss on Drying	NMT 5.0%.	0.2 %
07	Particulate Matter		
	≥10µm ≥ 25µm	NMT 6000 no. of particles per container. NMT 600 no. of particles per container.	2667 particles per container. 5 particles per container.
08	Uniformity of Weight	For information only	197 mg
09	Sterility	Should be Sterile.	Sterile

Function	Prepared By	Reviewed By	Approved By
Name	Harshali Rajput	Mayur D. Suryawanshi	Siddharth Singh
Designation-Department	Officer -QC	Officer-Micro	Sr. Executive-QC
Sign & Date	 20/12/2023	 20/12/2023	 20/12/2023

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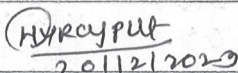
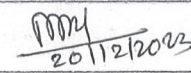
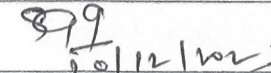


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Format No.: KBPL/QC/030/F03-00			
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Mfg. Date	Oct-2023	Sampling Quantity	80 Vials
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Batch Size	2 Kg	Date of Analysis	19/10/2023
Pack Size/Type	1 X 10 ml Vial	Date of Release	03/11/2023
Ref. Spec. No.	SPC/FG00000032-00	Page No.	Page 3 of 3

Sr. No.	Test	Specification	Result
10	Bacterial Endotoxins	NMT 43.75 EU/ml of Colistimethate Sodium.	Less than 43.75 EU/ml.
11	Assay (Microbiological) Each vial contain:	Not Less Than 90.0% and Not More Than 120.0% of stated amount of Colistimethate Sodium.	107.9 %

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	Mayur D. Suryawanshi	Siddharth Singh
Designation-Department	Officer -QC	Officer-Micro	Sr. Executive-QC
Sign & Date	 20/12/2023	 20/12/2023	 20/12/2023

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