

Format No.: KBPL/QC/030/F03-01			
Product Name	COLISTICAN 1 Injection		
Generic Name	Colistimethate Sodium for Injection IP 1 MIU/ Vial		
Batch No.	K15524005	A.R. No.	FP/08/24/00041
Mfg. Date	Aug-2024	Sampling Quantity	65 Vials
Exp. Date	Jul-2026	Sampling Date	31/08/2024
Batch Size	1 Kg	Date of Analysis	31/08/2024
Pack Quantity	NA	Date of Release	15/09/2024
Ref. Spec. No.	FP/SPC/0063-00	Page No.	Page 1 of 2
Pack Size/Type	1 Vial		

Sr. No.	Test	Specification	Result
1.	Description	A white or almost white, crystalline powder.	Almost white, crystalline powder.
2.	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 is produced.	Complies
C.	By Chemical Method (Sulphate)	The solution should decolorize and white precipitate is formed	Complies
D.	By Chemical Method (Sodium Salts)	No precipitate is formed.	Complies
3.	pH	Between 6.5 to 8.5	8.1
4.	Clarity and Colour of Solution		
A.		The Solid dissolves completely, leaving no visible residue as undissolved matter.	Complies
B.		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
5.	Free Colistin	The solution is not more opalescent than opalescence standard OS2.	Complies
6.	Loss on Drying	NMT 5.0%.	2.3 %



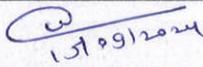
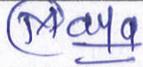
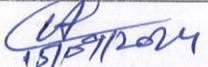
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QUALITY CONTROL
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

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7.	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container.	901 particles per container.
	≥ 25 µm	NMT 600 no. of particles per container.	7 particles per container.
8.	Uniformity of Weight	As per current BMR limit.	70.0 mg
9.	Sterility	Should be sterile.	Sterile
10.	Bacterial Endotoxins	NMT 43.75 EU/ml of Colistimethate Sodium	Less than 43.75 EU/ml
11.	Assay (Microbiological)	Not Less Than 90.0% and Not More Than 120.0% of stated amount of Colistimethate Sodium.	104.0 %

CONCLUSION: The Finish Product Sample ~~Does not complies~~ ^{Complies} as per ~~IP/BP/USP~~ ^{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	 15/09/2024	 15/09/2024	 15/09/2024

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
Maharashtra, India

