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QUALITY CONTROL CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	**Colistican 3 MIU**		
Generic Name	**Colistimethate Sodium for Injection IP 3 MIU/ Vial**		
Batch No.	K03224006	**A.R. No.**	FP/09/24/00052
Mfg. Date	Sep-2024	**Sampling Quantity**	65 Vials
Exp. Date	Aug-2026	**Sampling Date**	30/09/2024
Batch Size	1 Kg	**Date of Analysis**	30/09/2024
Pack Quantity	NA	**Date of Release**	11/10/2024
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.	A 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	7.4
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%.	0.13%

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Sr. No.	Test	Specification	Result
7.	**Particulate Matter**		
	≥ 10 µm	NMT 6000 no. of particles per container.	458 no. of particles per container.
	≥ 25 µm	NMT 600 no. of particles per container.	52 no. of particles per container.
8.	**Uniformity of Weight**	As per current BMR limit.	228.2 mg
9.	**Sterility**	Should be sterile.	*Under observation
10.	**Bacterial Endotoxins**	NMT 43.75 EU/ml of Colistimethate Sodium.	LT 43.75 EU/ml of Colistimethate Sodium.
11.	**Assay (Microbiological)**	Not Less Than 90.0% and Not More Than 120.0% of stated amount of Colistimethate Sodium.	104.29%

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

*Sterility test is under observation.

Function	Prepared By	Reviewed By	Approved By
Name	**Vaishnavi Bhamare**	**Kushal Deshmukh**	**Avnish Kumar**
Designation-Department	**Officer-QC**	**Asst. Manager QC**	**Manager-QC**
Sign & Date	11/10/2024	11/10/2024	11/10/2024

Kaliberr BioScience Pvt. Ltd.

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