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QUALITY CONTROL CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	**COLISTICAN 2**		
Generic Name	**Colistimethate Sodium for Injection IP 2 MIU/ Vial**		
Batch No.	K15624001	**A.R. No.**	FP/05/24/00012
Mfg. Date	May-2024	**Sampling Quantity**	65 Vials
Exp. Date	Apr-2026	**Sampling Date**	14/05/2024
Batch Size	1 Kg X 2 Lot	**Date of Analysis**	14/05/2024
Pack Quantity	NA	**Date of Release**	29/05/2024
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	7.7
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

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6.	**Loss on Drying**	NMT 5.0%.	1.7 %
7.	**Particulate Matter**		
	≥ 10 µm	NMT 6000 no. of particles per container.	607 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.	130.2 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.	103.7 %

CONCLUSION: The Finish Product Sample Complies / ~~Does not comp~~lies 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**	**Manger-QC**
Sign & Date	Maya 14/06/2024	Kushal 14/06/2024	14/06/2024

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

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