

Format No.: KBPL/QC/030/F03-01

<b>Product Name</b>	<b>COLISTICAN 1 Injection</b>		
<b>Generic Name</b>	<b>Colistimethate Sodium for Injection IP 1 MIU/ Vial</b>		
<b>Batch No.</b>	K15524004	<b>A.R. No.</b>	FP/06/24/00043
<b>Mfg. Date</b>	Jun-2024	<b>Sampling Quantity</b>	75 Vials
<b>Exp. Date</b>	May-2026	<b>Sampling Date</b>	27/06/2024
<b>Batch Size</b>	1 Kg X 2 Lot	<b>Date of Analysis</b>	28/06/2024
<b>Pack Quantity</b>	NA	<b>Date of Release</b>	12/07/2024
<b>Ref. Spec. No.</b>	FP/SPC/0063-00	<b>Page No.</b>	Page 1 of 2
<b>Pack Size/Type</b>	1 Vial		

Sr. No.	Test	Specification	Result
1.	<b>Description</b>	A white or almost white, crystalline powder.	Almost white, crystalline powder.
2.	<b>Identification</b>		
A.	<b>By TLC</b>	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.	<b>By Chemical Method</b>	A purple colour is produced.	Complies
C.	<b>By Chemical Method (Sulphate)</b>	The solution should decolorize and white precipitate is formed	Complies
D.	<b>By Chemical Method (Sodium Salts)</b>	No precipitate is formed.	Complies
3.	<b>pH</b>	Between 6.5 to 8.5	7.1
4.	<b>Clarity and Colour of Solution</b>		
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.	<b>Free Colistin</b>	The solution is not more opalescent than opalescence standard OS2.	Complies
6.	<b>Loss on Drying</b>	NMT 5.0%.	0.06 %




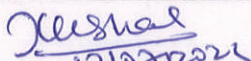
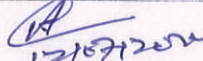
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## QUALITY CONTROL CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

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Pack Size/Type	1 Vial		

7.	<b>Particulate Matter</b>		
	$\geq 10 \mu\text{m}$	NMT 6000 no. of particles per container.	785 particles per container.
	$\geq 25 \mu\text{m}$	NMT 600 no. of particles per container.	2 particles per container.
8.	<b>Uniformity of Weight</b>	As per current BMR limit.	73.9 mg
9.	<b>Sterility</b>	Should be sterile.	Sterile
10.	<b>Bacterial Endotoxins</b>	NMT 43.75 EU/ml of Colistimethate Sodium	Less than 43.75 EU/ml
11.	<b>Assay (Microbiological)</b>	Not Less Than 90.0% and Not More Than 120.0% of stated amount of Colistimethate Sodium.	104.5 %

**CONCLUSION:** The Finish Product Sample Complies / ~~Does not complies~~ as per ~~HH/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	 12/07/2024	 12/07/2024	 12/07/2024

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