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QUALITY CONTROL CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	**Vecanium 4 Injection**		
Generic Name	**Vecuronium Bromide Injection IP 4 mg per vial**		
Batch No.	K09825002	**A.R. No.**	FP/03/25/00023
Mfg. Date	Mar-2025	**Sampling Quantity**	65 vials
Exp. Date	Feb-2027	**Sampling Date**	20/03/2025
Batch Size	37000 vials	**Date of Analysis**	20/03/2025
Pack Quantity	NA	**Date of Release**	26/03/2025
Ref. Spec. No.	FP/SPC/0122-00	**Page No.**	Page 1 of 2
Pack Size/Type	1 Vial		

Sr. No.	Test	Specification	Result
1.	Description	A white to off white lyophilized mass.	A white lyophilized mass.
2.	Identification		
A.	By HPLC	In the Related substance, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (a).	Complies.
B.	By Light absorption	NMT 0.1 at 420 nm	0.035
3.	pH	3.5 to 4.5	4.1
4.	Water	NMT 3.0%	0.0 %
5.	Related Substances (By HPLC)		
	Area of any peaks due to vecuronium bromide mono impurity and diol impurity	NMT 1.0%	Not detected
	Total impurity	NMT 2.0%	Not detected
6.	Assay (By HPLC)	Not less than 90.0% and not more than 110.0% of stated amount of Vecuronium Bromide.	102.4 %
7.	Particulate Matter		
	≥ 10 µm	NMT 6000 particles per container	70 particles per container
	≥ 25 µm	NMT 600 particles per container	3 particles per container

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8.	Sterility	Should be sterile	*Under observation
9.	Bacterial Endotoxins	NMT 50 EU/mg of Vecuronium Bromide.	Less than 50 EU/mg

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

Note: *Sterility test is under observation.

Function	Prepared By	Reviewed By	Approved By
Name	Pranita Wadje	Maya Sirsat	Avnish Kumar
Designation-Department	Officer - QC	Executive - QC	Manager - QC
Sign & Date	26/03/2025	26/03/2025	26/03/2025

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