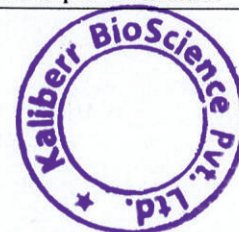


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**QUALITY CONTROL
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Format No.: KBPL/QC/030/F03-01			
Product Name	Vecanium 4 Injection		
Generic Name	Vecuronium Bromide Injection IP 4 mg per vial		
Batch No.	K09824006	A.R. No.	FP/12/24/00037
Mfg. Date	Dec-2024	Sampling Quantity	65 vials
Exp. Date	Nov-2026	Sampling Date	30/12/2024
Batch Size	37000 vials	Date of Analysis	30/12/2024
Pack Quantity	NA	Date of Release	13/01/2025
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	0.001
3.	pH	3.5 to 4.5	4.2
4.	Water	NMT 3.0%	0.14930%
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.	99.0 %
7.	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container	207 particles per container
	≥ 25 µm	NMT 600 no. of particles per container	9 particles per container



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Pack Size/Type	1 Vial		

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

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

Function	Prepared By	Reviewed By	Approved By
Name	Vaishnavi Bhamare	Maya Sirsat	Avnish Kumar
Designation- Department	Officer-QC	Executive-QC	Manager-QC
Sign & Date	<i>phange</i> 16/01/2025	<i>Maya</i> 16/01/2025	<i>AK</i> 16/01/2025

Kaliberr BioScience Pvt. Ltd.

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