

**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.	K09824004	A.R. No.	FP/04/24/00004
Mfg. Date	Mar-2024	Sampling Quantity	65 vials
Exp. Date	Feb-2026	Sampling Date	04/04/2024
Batch Size	37000 vials	Date of Analysis	05/04/2024
Pack Quantity	NA	Date of Release	19/04/2024
Ref. Spec. No.	SPC/FG00000098-00	Page No.	Page 1 of 2
Pack Size/Type	1 Vial		

Sr. No.	Test	Specification	Result
01	Description	A white to off white lyophilized mass	A white lyophilized mass
02	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	0.013
03	pH	3.5 to 4.5	4.4
04	Particulate Matter		
	$\geq 10\mu\text{m}$ $\geq 25\mu\text{m}$	NMT 6000 no. of particle per container. NMT 600 no. of particle per container.	34 particles per container. 1 particle per container.
05	Water	NMT 3.0%	0.5 %
06	Bacterial Endotoxin	NMT 50 EU/mg of Vecuronium Bromide.	Less than 50 EU/mg.
07	Sterility	Should be Sterile.	Sterile


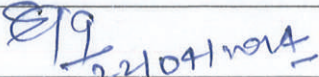
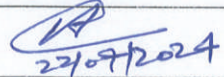


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08	Related substance (By HPLC)		
A	Mono Impurity	NMT 1.0 %	Not detected
B	Diol Impurity	NMT 1.0 %	Not detected
C	Sum of all area of all secondary peaks	NMT 2.0 %	Not detected
09	Assay (By HPLC)	Not less than 90.0% and not more than 110.0% of stated amount of vecuronium bromide	99.8 %

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

Function	Prepared By	Reviewed By	Approved By
Name	Maya Sirsat	Siddharth Singh	Avnish Kumar
Designation-Department	Executive-QC	Sr. Executive-QC	Manager-QC
Sign & Date	 22/04/2024	 22/04/2024	 22/04/2024

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