

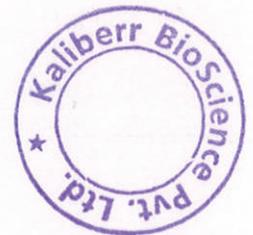
# kaliberr

QUALITY CONTROL  
CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)

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

<b>Product Name</b>	Vecanium 4 Injection		
<b>Generic Name</b>	Vecuronium Bromide Injection IP 4 mg per vial		
<b>Batch No.</b>	K09824005	<b>A.R. No.</b>	FP/07/24/00036
<b>Mfg. Date</b>	Jul-2024	<b>Sampling Quantity</b>	65 vials
<b>Exp. Date</b>	Jun-2026	<b>Sampling Date</b>	23/07/2024
<b>Batch Size</b>	37000 vials	<b>Date of Analysis</b>	23/07/2024
<b>Pack Quantity</b>	NA	<b>Date of Release</b>	06/08/2024
<b>Ref. Spec. No.</b>	SPC/FG00000098-00	<b>Page No.</b>	Page 1 of 2
<b>Pack Size/Type</b>	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	0.008
03	pH	3.5 to 4.5	4.2
04	Particulate Matter		
	≥10µm	NMT 6000 no. of particle per container.	60 particles per container.
	≥ 25µm	NMT 600 no. of particle per container.	1 particle per container.
05	Water	NMT 3.0%	1.4 %
06	Bacterial Endotoxin	NMT 50 EU/mg of Vecuronium Bromide.	Less than 50 EU/mg.
07	Sterility	Should be Sterile.	Sterile



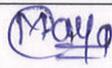
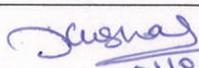
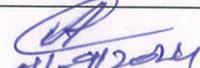
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08	Related substance (By HPLC)		
A	Mono Impurity	NMT 1.0 %	Not detected
B	Diol Impurity	NMT 1.0 %	Not detected
C	Sum of all area of all secondary peaks	NMT 2.0 %	Not detected
09	Assay (By HPLC)	Not less than 90.0% and not more than 110.0% of stated amount of vecuronium bromide	101.4 %

**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	 01/09/2024	 01/09/2024	 01/09/2024

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