

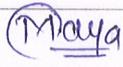
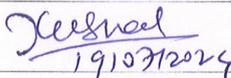
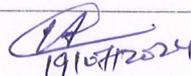
## QUALITY CONTROL CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	TERLISIN Injection		
Generic Name	Terlipressin Injection 1 mg / 10 ml		
Batch No.	K09424002	A.R. No.	FP/07/24/00011
Mfg. Date	Jul-2024	Sampling Quantity	45 Ampoules
Exp. Date	Jun-2026	Sampling Date	07/07/2024
Batch Size	100 Litre	Date of Analysis	07/07/2024
Pack Quantity	NA	Date of Release	19/07/2024
Ref. Spec. No.	SPC/FG00000094-00	Page No.	Page 1 of 1
Pack Size/Type	1 X 10 ml Ampoule		

Sr. No.	Test	Specification	Result
01	Description	A clear colourless Solution	A clear colourless Solution
02	Identification		
A.	(BY HPLC)	The retention time of standard solution correspond to that exhibited to retention time of sample solution	Complies
03	pH	Between 4.0 to 5.0	4.9
04	Particulate Matter		
	≥10µm	NMT 6000 no. of particles per container.	53 particles per container.
	≥25µm	NMT 600 no. of particles per container.	0 particle per container.
05	Extractable Volume	NLT 10 ml	10.1 ml
06	Sterility	Should be Sterile.	*Under observation
07	Bacterial Endotoxin	NMT 2.5 EU/mg of Terlipressin.	Less than 2.5 EU/mg
08	Assay (By HPLC)	NLT 90.0% and NMT 110.0% of Terlipressin.	102.0 %

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

**Note:** \*Sterility test is under observation.

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	 19/07/2024	 19/07/2024	 19/07/2024

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