

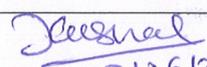
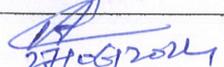
# kaliberr

QUALITY CONTROL  
CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	THIACAN 200 Injection		
Generic Name	Thiamine Injection IP 100 mg/ml		
Batch No.	K10724004	A.R. No.	FP/06/24/00016
Mfg. Date	Jun-2024	Sampling Quantity	80 Ampoules
Exp. Date	May-2026	Sampling Date	13/06/2024
Batch Size	200 Lit.	Date of Analysis	13/06/2024
Pack Quantity	NA	Date of Release	27/06/2024
Ref. Spec. No.	SPC/FG00000107-00	Page No.	Page 1 of 1
Pack Size/Type	NA		

Sr. No.	Test	Specification	Result
01	Description	A clear Solution.	A clear solution.
02	Identification		
A	By Chemical Method	The upper layer exhibits an intense light blue fluorescence, particularly under ultraviolet light at 365 nm.	Complies
B	By Chemical Method	No violet colour produced in the upper layer.	Complies
03	pH	Between 2.5 to 4.5	3.2
04	Particulate Matter		
	$\geq 10\mu\text{m}$	NMT 6000 no. of particles per container.	99 particles per container.
	$\geq 25\mu\text{m}$	NMT 600 no. of particles per container.	8 particles per container.
05	Extractable Volume	NLT 2 ml	2.1 ml
06	Sterility	Should be Sterile.	Sterile
07	Bacterial Endotoxin	NMT 3.5 EU/mg of Thiamine Hydrochloride.	Less than 3.5 EU/mg
08	Assay (By HPLC)	Not less than 95.0% to not more than 110.0% of the stated amount of Thiamine Hydrochloride	103.8 %
09	Preservative Test (Benzyl Alcohol – By HPLC)	NLT 90.0 % to NMT 110.0 % of Labelled quantity	100.3 %

**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	 27/06/2024	 27/06/2024	 27/06/2024

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