

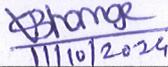
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QUALITY CONTROL
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	Thiacan 200 Injection		
Generic Name	Thiamine Injection IP 100 mg/ml		
Batch No.	K10724005	A.R. No.	FP/09/24/00006
Mfg. Date	Aug-2024	Sampling Quantity	60 Ampoules
Exp. Date	Jul-2026	Sampling Date	06/09/2024
Batch Size	200 Lit. X 2 Lot	Date of Analysis	06/09/2024
Pack Quantity	NA	Date of Release	20/09/2024
Ref. Spec. No.	FP/SPC/0120-00	Page No.	Page 1 of 1
Pack Size/Type	NA		

Sr. No.	Test	Specification	Result
1.	Description	A Clear Solution.	A Clear Solution.
2.	Identification		
2.1.	By Chemical Method	The upper layer exhibits an intense light blue fluorescence, particularly under ultraviolet light at 365 nm.	Complies
2.2.	By Chemical Method	No violet colour is produced in upper layer.	Complies
3.	pH	Between 2.5 to 4.5	2.9
4.	Extractable Volumes	NLT as per label claim.	2.1 ml
5.	Assay (By HPLC)	Not less than 95.0% and not more than 110.0% of the stated amount of Thiamine Hydrochloride.	103.1 %
6.	Preservative Test (Benzyl Alcohol) (By HPLC)	NLT 90.0% to NMT 110.0% of labelled quantity.	99.1 %
7.	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container.	88 particles per container
	≥ 25 µm	NMT 600 no. of particles per container.	3 particles per container
8.	Sterility	Should be sterile.	Sterile
9.	Bacterial Endotoxins	NMT 3.5 Endotoxin Unit per mg of thiamine hydrochloride.	Less than 3.5 EU/mg

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

Function	Prepared By	Reviewed By	Approved By
Name	Vaishnavi Bhamare	Kushal Deshmukh	Avnish Kumar
Designation-Department	Officer-QC	Asst. Manager-QC	Manager-QC
Sign & Date	 11/10/2024	 11/10/2024	 11/10/2024

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