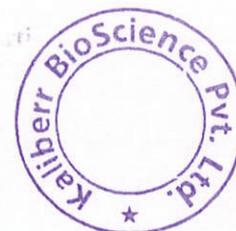


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QUALITY CONTROL
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	COTRIXOLE Injection		
Generic Name	Sterile Co-Trimoxazole Concentrate infusion BP 5 ml		
Batch No.	K14324007	A.R. No.	FP/06/24/00004
Mfg. Date	May-2024	Sampling Quantity	80 Ampoules
Exp. Date	Apr-2026	Sampling Date	02/06/2024
Batch Size	50 Lit. X 2 Lot	Date of Analysis	03/06/2024
Pack Quantity	NA	Date of Release	17/06/2024
Ref. Spec. No.	FP/SPC/0037-00	Page No.	Page 1 of 2
Pack Size/Type	5 ml Ampoule		

Sr. No.	Test	Specification	Result
01	Description	A colourless or slightly yellow solution.	A colourless solution.
02	Identification		
A	By IR (Sulfamethoxazole)	The infrared absorption spectrum of the residue, is concordant with the reference spectrum of sulfamethoxazole.	Complies
B	By IR (Trimethoprim)	The infrared absorption spectrum of the residue, is concordant with the reference spectrum of trimethoprim.	Complies
C	By Thin-layer chromatography	One of the principal spots in the chromatogram obtained with solution corresponds to the spot in the chromatogram obtained with solution and the other corresponds to that in the chromatogram obtained with solution.	Complies
03	pH	Between 9.5 to 11.0	10.2
04	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container.	297 particles per container.
	≥ 25 µm	NMT 600 no. of particles per container.	66 particles per container.
05	Extractable Volumes	NLT 5 ml	5.0 ml
06	Sterility	Should be sterile.	Sterile
07	Bacterial Endotoxins	NMT 0.5 EU/ml	Less than 0.5 EU/ ml



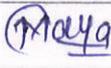
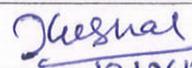
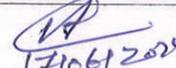
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Pack Size/Type	5 ml Ampoule		

08	Assay		
A	For trimethoprim (By UV method) Each ml contains: Trimethoprim BP - 16mg	92.5 to 107.5% of the stated amount of trimethoprim.	101.1 %
B	For sulfamethoxazole (By titrimetric method) Each ml contains: Sulfamethoxazole BP -80mg	92.5 to 107.5% of the stated amount of sulfamethoxazole.	98.7 %

CONCLUSION: The Finish Product Sample Complies / ~~Does not complies~~ as per ~~HH/HP/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	 17/06/2024	 17/06/2024	 17/06/2024

Kaliberr BioScience Pvt. Ltd.

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