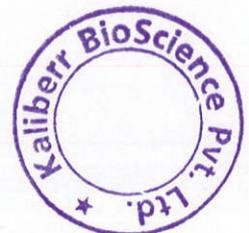


Format No.: KBPL/QC/030/F03-01			
Product Name	COTRIXOLE Injection		
Generic Name	Sterile Co-Trimoxazole Concentrate infusion BP 5 ml		
Batch No.	K14324009	A.R. No.	FP/09/24/00029
Mfg. Date	Sep-2024	Sampling Quantity	45 Ampoules
Exp. Date	Aug-2026	Sampling Date	19/09/2024
Batch Size	50 Lit. X 2 Lot	Date of Analysis	19/09/2024
Pack Quantity	NA	Date of Release	29/09/2024
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.	430 particles per container.
	≥ 25 µm	NMT 600 no. of particles per container.	12 particles per container.
05	Extractable Volumes	NLT 5 ml	5.1 ml
06	Sterility	Should be sterile.	*Under Observation
07	Bacterial Endotoxins	NMT 0.5 EU/ml	Less than 0.5 EU/ ml



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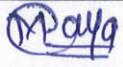
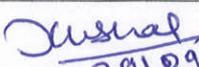
QUALITY CONTROL
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	COTRIXOLE Injection		
Generic Name	Sterile Co-Trimoxazole Concentrate infusion BP 5 ml		
Batch No.	K14324009	A.R. No.	FP/09/24/00029
Mfg. Date	Sep-2024	Sampling Quantity	45 Ampoules
Exp. Date	Aug-2026	Sampling Date	19/09/2024
Batch Size	50 Lit. X 2 Lot	Date of Analysis	19/09/2024
Pack Quantity	NA	Date of Release	29/09/2024
Ref. Spec. No.	FP/SPC/0037-00	Page No.	Page 2 of 2
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.	102.1 %
B	For sulfamethoxazole (By titrimetric method) Each ml contains: Sulfamethoxazole BP -80mg	92.5 to 107.5% of the stated amount of sulfamethoxazole.	101.2 %

CONCLUSION: The Finish Product Sample Complies / ~~Does not comply~~ as per IH/HP/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	 29/09/2024	 29/09/2024	 29/09/2024

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