



DERREN HEALTHCARE PRIVATE LIMITED

PLOT NO 33,35/P & 36/P, XCELON INDUSTRIAL PARK,
SARKHEJ-BAVLA HIGHWAY, VILL. VASNA - CHACHARWADI,
TA : SANAND. DIST.AHMEDABAD - 382213, GUJARAT,INDIA

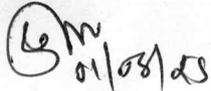
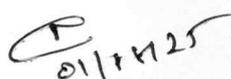
FINISHED PRODUCT ANALYTICAL TEST REPORT

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Product Name	COTRIXOLE INJECTION 5 ML	Specification No.	DHPL/FP/SPEC/SULFA/06/00
Generic Name	TRIMETHOPRIM 80MG + SULPHAMETHOXAZOLE 400MG BP	Batch No. /Lot No.	DN25004
BENZYL ALCOHOL 1% V/V SULPHAMETHOXAZOLE IP.....400 MG Trimethoprim IP80 MG Each 5 ml contain;		Mfg. Dt.	07/2025
		Exp. Dt.	06/2027
		Receipt Dt.	18/07/2025
		Release Dt.	01/08/2025
		Sample Size	41.000 Nos
		Mfg. Lic. No.	G/28/1862
		A.R. No.	BP/25/0178
Analysis	DHIREN MUKESHBHAI PATEL	Manufactured By	DERREN
		Theoretical Yield/Batch Size	32,692.000 Ampoule

Sr.	Test	Limit	Result
1	Description	A colorless or slightly yellow solution.	A slightly yellow solution.
2	Extractable volume	NLT 5.0 ml	5.5 ml
3	pH	9.5 to 11.0	10.1
4	Identification by TLC	One of the principal spots in the chromatogram obtained with solution (1) corresponds to the spot in the chromatogram obtained with solution (2) and the other corresponds to that in the chromatogram obtained with solution (3).	One of the principal spots in the chromatogram obtained with solution (1) corresponds to the spot in the chromatogram obtained with solution (2) and the other corresponds to that in the chromatogram obtained with solution (3).
5	Bacterial endotoxins	Less than 0.20 EU/ml	Less than 0.20 EU/ml
6	Particulate matter By Visual inspection By light obscuration method	 The solution should be free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=NMT 6000/Container > 25 Microns=NMT 600/Container	 The solution is free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=93.3/Container > 25 Microns=2.67/Container
7	Sterility test	Should be sterile	sterile
8	Assay	.	.

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per BP specification.

Prepared By  01/08/25	Checked By  01/08/25	Approved By  01/08/25
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DHIRENP 01/08/2025 10:58 AM

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