



# 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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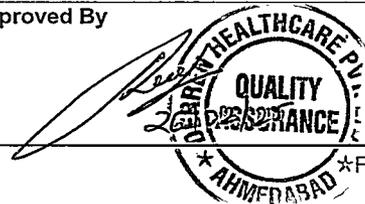
<b>Product Name</b>	CORTRIXOLE INJECTION 5 ML	<b>Specification No.</b>	DHPL/FP/SPEC/SULFA/06/00
<b>Generic Name</b>	TRIMETHOPRIM 80MG + SULPHAMETHOXAZOLE 400MG BP	<b>Batch No. /Lot No.</b>	DN25001
BENZYL ALCOHOL 1% V/V SULPHAMETHOXAZOLE IP.....400 MG Trimethoprim IP .....80 MG Each 5 ml contain;		<b>Mfg. Dt.</b>	02/2025
		<b>Exp. Dt.</b>	01/2027
		<b>Receipt Dt.</b>	12/02/2025
		<b>Release Dt.</b>	26/02/2025
		<b>Sample Size</b>	41.000 Nos
		<b>Mfg. Lic. No.</b>	G/28/1862
		<b>A.R. No.</b>	FP/25/0028
	<b>Manufactured By</b>	DERREN	
<b>Analysis</b>	DHIREN MUKESHBHAI PATEL	<b>Theoretical Yield/Batch Size</b> 28,840.000 Ampoule	

Sr.	Test	Limit	Result
1	Description	A colorless or slightly yellow solution.	A slightly yellow solution.
2	Extractable volume	NLT 5.0 ml	5.2 ml
3	pH	9.5 to 11.0	10.2
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=98.33/Container > 25 Microns=7.00/Container

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

<b>Prepared By</b>  26/02/25	<b>Checked By</b>  26/02/25	<b>Approved By</b>  26/02/25
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<b>Analysis</b>	DHIREN MUKESHBHAI PATEL	<b>Manufactured By</b>	DERREN
		<b>Theoretical Yield/Batch Size</b>	28,840.000 Ampoules

Sr.	Test	Limit	Result
7	Sterility test	Should be sterile	sterile
8	Assay		
	Assay of trimethoprim	92.5 to 107.5%	100.6%
	Assay of sulfamethoxazole	92.5 to 107.5%	100.5%

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

<b>Prepared By</b>  26/02/25	<b>Checked By</b>  26/02/25	<b>Approved By</b> 
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