



# 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>	CANPAM INJECTION 20 ML	<b>Specification No.</b>	DHPL/FP/SPEC/PRALI/06/00
<b>Generic Name</b>	PRALIDOXIME IODIDE 500 MG	<b>Batch No. /Lot No.</b>	CM25010
Each ml contains: 2-Pyridine Aldoxime Methiodide.....25 mg Water for injection.....Q.S.		<b>Mfg. Dt.</b>	10/2025
		<b>Exp. Dt.</b>	09/2027
		<b>Receipt Dt.</b>	18/10/2025
		<b>Release Dt.</b>	01/11/2025
		<b>Sample Size</b>	36.000 Ampoule
		<b>Mfg. Lic. No.</b>	G/28/1862
		<b>A.R. No.</b>	FP/25/0255
		<b>Manufactured By</b>	DERREN
<b>Analysis</b>	VIBHA KAMLESHBHAI PATEL	<b>Theoretical Yield/Batch Size</b>	12,195.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear, pale yellow solution free from visible particles and fibers.	Clear, pale yellow solution free from visible particles and fibers.
2	Extractable volume	NLT 20.0 ml	20.1 ml
3	pH	2.0 to 5.0	4.20
4	Bacterial Endotoxin test	NMT 13.25 EU/mg of Pralidoxime iodide	less than 13.25 EU/mg of Pralidoxime iodide
5	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=145.00/Container > 25 Microns=15.00/Container
6	Sterility test	Should be sterile	sterile
7	Assay by UVEach ml contains Pralidoxime iodide 25mg/ml	90.0% to 110.0% of the labeled amount of Pralidoxime iodide	98.3% of the labeled amount of Pralidoxime iodide

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

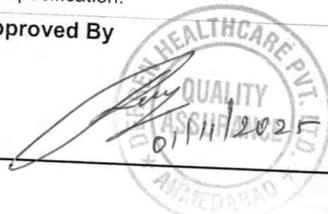
Prepared By

*[Signature]*  
01/11/25

Checked By

*[Signature]*  
01/11/25

Approved By



VIBHAP 01/11/2025 10:23 AM

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