



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

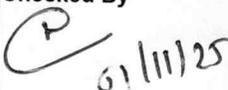
FINISHED PRODUCT ANALYTICAL TEST REPORT

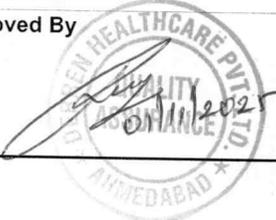
Page 1 of 1

Product Name	CANPAM INJECTION 20 ML	Specification No.	DHPL/FP/SPEC/PRALI/06/00
Generic Name	PRALIDOXIME IODIDE 500 MG	Batch No. /Lot No.	CM25009
Each ml contains: 2-Pyridine Aldoxime Methiodide.....25 mg Water for injection.....Q.S.		Mfg. Dt.	10/2025
		Exp. Dt.	09/2027
		Receipt Dt.	18/10/2025
		Release Dt.	01/11/2025
		Sample Size	36.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0254
		Manufactured By	DERREN
Analysis	VIBHA KAMLESHBHAI PATEL	Theoretical Yield/Batch Size	16,585.000 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	20.0 ml
3	pH	2.0 to 5.0	4.43
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=71.00/Container > 25 Microns=2.00/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	98.6% 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  01/11/25	Checked By  01/11/25	Approved By  01/11/25
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VIBHAP 01/11/2025 10:23 AM

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