DERREN HEALTHCARE PVT. LTD.
Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi, Ahmedabad-382 213, Gujarat (India)

CERTIFICATE OF ANALYSIS

(FINISHED PRODUCT)

Name of Product	Pralidoxime iodide Injection 25 mg/ml(CANPAM)		
Batch No.	CM24002	**A.R. No.**	FP/24/0070
Mfg. Date	08/24	**Exp. Date**	07/26
Sampled Qty.	36 Nos.	**Date of Analysis**	10/08/24
Batch Size	350 Ltr.	**Fill Volume**	20.0 ml
Container Type	Amber Glass Ampoule	**Date of Release**	24/08/24
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
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	20.5 ml	NLT 20.0 ml
4	pH	2.52	2.0 to 3.0
5	Bacterial endotoxin	Less than 13.25 EU/mg	NMT 13.25 EU/mg of Pralidoxime iodide
6	Particulate matter		
6.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
6.2	By Light Obscuration Method	≥10 microns = 817.33/Container ≥25 Microns = 36.00/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Assay by UV Each ml contains Pralidoxime iodide 25mg/ml	97.3% of the labeled amount of Pralidoxime iodide	90.0% to 110.0% of the labeled amount of Pralidoxime iodide

Conclusion: The above sample complies as per In –House specification.
In the opinion of the undersigned the sample referred to above is **of standard / ~~not of standard~~** quality as defined in the act and the rules made there under for the reasons given above.

Prepared By	Checked By	Approved By
24/08/24 QC Executive	24/08/24 QC Sr. Executive	24/08/24 QA MANAGER