



# 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>	NERVERON INJ 20 ML	<b>Specification No.</b>	DHPL/FP/SPEC/EDARA/01/00
<b>Generic Name</b>	EDARAVONE INJECTION	<b>Batch No. /Lot No.</b>	BB25005
		<b>Mfg. Dt.</b>	11/2025
		<b>Exp. Dt.</b>	10/2027
		<b>Receipt Dt.</b>	17/11/2025
		<b>Release Dt.</b>	13/12/2025
		<b>Sample Size</b>	36.000 Ampoule
		<b>Mfg. Lic. No.</b>	G/28/1862
		<b>A.R. No.</b>	FP/25/0298.
<b>Analysis</b>	PRAKASH DHIRUBHAI MAKWANA	<b>Manufactured By</b>	DERREN
		<b>Theoretical Yield/Batch Size</b>	9,024.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear, colourless liquid free from visible particles and fibers.	Clear, colourless liquid free from visible particles and fibers.
2	Extractable volume	NLT 20.0 ml	20.0 ml
3	Identification by UV	Maximum between 238 nm to 242 nm	Complies (Maximum between 238 nm to 242 nm)
4	pH	3.0 to 5.5	4.5
5	Purity ( Related Substance) Any other Peak	NMT 3 ppm	Not Detected
6	Bacterial Endotoxin test	Less than 5.0 EU/mg	Less than 5.0 EU/mg
7	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=70.67/Container > 25 Microns=2.67/Container
8	Sterility test	Should be sterile	sterile
9	Assay	95.0% to 105.0% of the stated amount of Edaravone	99.3% of the stated amount of Edaravone

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

<b>Prepared By</b> D 13/12/25	<b>Checked By</b> P 13/12/25	<b>Approved By</b> P 13/12/2025
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PRAKASHM 13/12/2025 01:20 PM

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