



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	NERVERON INJ 20 ML	Specification No.	DHPL/FP/SPEC/EDARA/01/00
Generic Name	EDARAVONE INJECTION	Batch No. /Lot No.	BB25002
		Mfg. Dt.	03/2025
		Exp. Dt.	02/2027
		Receipt Dt.	15/03/2025
		Release Dt.	03/04/2025
		Sample Size	36.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/01/0001
		Manufactured By	DERREN
Analysis	VIBHA KAMLESHBHAI PATEL	Theoretical Yield/Batch Size	5,609.000 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	20.5 ml
3	Identification by UV	Maximum between 238 nm to 242 nm	Maximum At A 239.5 nm
4	pH	3.0 to 5.5	3.98
5	Purity (Related Substance) Any other Peak	NMT 3 ppm	Complies
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 should be free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=178.67/Container > 25 Microns= 10.67/Container
8	Sterility test	Should be sterile	sterile
9	Assay	95.0% to 105.0% of the stated amount of Edaravone	98.5 %

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

Prepared By

[Signature]
03/04/25

Checked By

[Signature]
03/04/25

Approved By

[Signature]
03/04/2025
DERREN HEALTHCARE PRIVATE LIMITED
AHMEDABAD

VIBHAP 03/04/2025 05:04 PM

FgAnlCert02