



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)

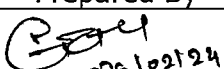
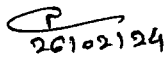

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of Product	Edaravone Injection 1.5 mg/ml		
Batch No.	BB24001	A.R. No.	FP/24/0010
Mfg. Date	02/24	Exp. Date	01/26
Sampled Qty.	05 Nos.	Date of Analysis	11/02/24
Batch Size	80 Ltr.	Date of Release	26/02/24
Container Type	Clear Glass Ampoule	Fill volume	20.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, colourless liquid free from visible particles and fibers.	Clear, colourless to yellowish liquid free from visible particles and fibers.
2	Extractable volume	20.0 ml	NLT 20.0 ml
3	Identification		
3.1	Identification by UV	Maxima At A 239.5 nm	Maximum between 238 nm to 242 nm
4	pH	3.8	3.0 to 5.5
5	Related Substance		
5.1	Any other Peak	Not detected	NMT 3 ppm
6	Bacterial endotoxin	Less than 5.0 Eu/mg	Less than 5.0 EU/mg
7	Particulate matter		
7.1	By Visual Inspection	The solution is free from particles of the foreign matter that is observed on visual inspection method.	The solution should be free from particles of the foreign matter that can be observed on visual inspection method.
7.2	By Light Obscuration Method	≥10 microns= 48.67 /Container ≥ 25 Microns= 1.33 /Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
8	Sterility test	Sterile	Should be sterile
9	Assay		
9.1	Each ml Contains: Edaravone 1.5 mg	100.2 %	95.0% to 105.0% of the stated amount of Edaravone.

Conclusion: The above sample complies as per JP 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
 20/02/24 QC EXECUTIVE	 20/02/24 QC Sr.EXECUTIVE	 20/02/24 QA MANAGER

