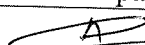
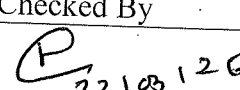



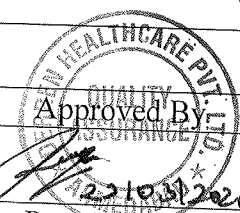
DERREN HEALTHCARE PVT. LTD.
 Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India
 Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,
 Ahmedabad-382 213, Gujarat (India)

CERTIFICATE OF ANALYSIS
 (FINISHED PRODUCT)

Name of Product	Lacosamide Injection 10 mg/ml		
Batch No.	EI26001	A.R. No.	FP/26/0117
Mfg. Date	03/26	Exp. Date	02/28
Sampled Qty.	36 Nos.	Date of Analysis	14/03/26
Batch Size	225 Ltr.	Date of Release	23/03/26
Container type.	Clear Glass Vial	Fill Volume	20.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, Colorless solution free from visible particles and fibers.	Clear, Colorless solution free from visible particles and fibers.
2	Extractable volume	20.0 ml	NLT 20.0 ml
3	Identification		
3.1	Identification A By HPLC	Complies	The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay
3.2	Identification by B HPLC	Complies	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
4	pH	4.77	Between 3.8 and 5.0
5	Bacterial endotoxin	Less than 0.5 EU/ml of Lacosamide.	Not more than 0.5 EU/ml of Lacosamide.
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	≥10microns= 400.00/Container ≥ 25 Microns= 17.33/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Organic Impurities	Not Detected	Lacosamide Related Compound D: NMT 0.80% Any individual unspecified degradation product: NMT 0.20% Total degradation products: NMT 2.0%

Prepared By	Checked By	Approved By
 23/03/26	 23/03/26	 23/03/26




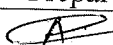

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8	Sterility test	Under Sterility	Should be sterile
9	Assay by HPLC		
9.1	Assay: Each ml Contains: Lacosamide injection	99.83% i.e. 9.983 mg/ml	90.0% to 105.0% of the labeled amount Lacosamide. i.e. 9.0 mg / mL to 10.5 mg / mL.

Conclusion: The above sample complies as per IP/BP/USP/EP/JP/IH 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	
 23/03/26	 23/03/26	