



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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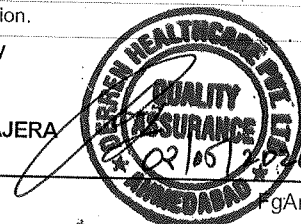
Product Name	COSEPIL INJECTION 20ML VIAL		
Generic Name	Lacosamide Injection USP 10mg/ml	Batch No. /Lot No.	EI26002
		Mfg. Dt.	04/2026
		Exp. Dt.	03/2028
		Receipt Dt.	18/04/2026
		Release Dt.	02/05/2026
		Sample Size	25.000 Vial
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0179
Analysis	KISHAN PATEL	Manufactured By	DERREN
		Theoretical Yield/Batch Size	10,975.000 Vial

Sr.	Test	Limit	Result
1	Description	Clear, Colorless solution free from visible particles and fibers.	Clear, Colorless solution free from visible particles and fibers.
2	Extractable volume	NLT 20.0 ml	20.1 ml
3	Identification		
	Identification A by HPLC	The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Complies
	Identification by B HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Complies
4	pH	Between 3.8 and 5.0	4.91
5	Bacterial endotoxin test	NMT 0.5 EU/ml of Lacosamide.	Less than 0.5 EU/ml of Lacosamide.
6	Particulate matter		
	By Visual inspection	The solution should be free from particles that can be observed by inspection with the unaided eye.	The solution is free from particles that is observed by inspection with the unaided eye.
	By light obscuration method	=10 microns=NMT 6000/Container =25 Microns=NMT 600/Container	=10 microns=1917.33/Container =25 Microns= 121.33/Container
7	Organic Impurity by HPLC	Lacosamide Related Compound D: NMT 0.80% Any individual unspecified degradation product: NMT 0.20% Total degradation products: NMT 2.0%	Lacosamide Related Compound D: Not Detected Any individual unspecified degradation product: Not Detected Total degradation products: Not Detected

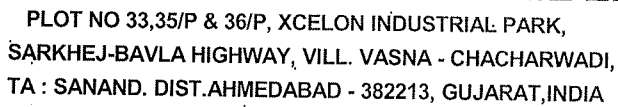
Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per USP specification.

Prepared By	Checked By	Approved By
KISHANP QC CHEMIST 02105126	for NUTAN PRAJAPATI QC HEAD 02105126	KRUNAL GAJERA QA HEAD

KISHAN 02/05/2026 02:31 PM



FgAnlCert02



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[illegible]

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Prepared By

Checked By

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