

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	LEVECAN (Levetiracetam Injection USP 100 mg/ml)		
Batch No.	24VG002	A.R. No.	FP240011
Batch Size	50000 Nos	Sample Quantity	50 Nos
Mfg. Date	07/2024	Date of Testing	08/07/2024
Exp. Date	06/2026	Date of Release	25/07/2024
Reference Batch No	NA	MFG. Lic. No.	N-MB-2023/263

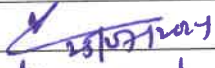
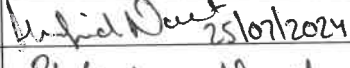
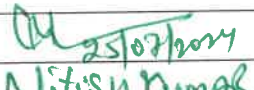
Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid.	Clear and colorless liquid.
2.	Identification (By HPLC)	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Complies
3.	pH	Between 5.0 to 6.0	5.58
4.	Organic Impurities Levetiracetam acid Any other Impurity Total Impurity	NMT 0.3% NMT 0.1% NMT 1.0%	Complies Complies Complies
5.	Extractable Volume	NLT 5.0 ml	5.0 ml
6.	Bacterial Endotoxins	NMT 0.175 USP Endotoxin Units/mg of levetiracetam	Less than 0.175 USP Endotoxin Units/mg of levetiracetam
7.	Particulate Matter (Visible Particles) (Sub Visible Particles) Particles of $\geq 10 \mu\text{m}$ Particles of $\geq 25 \mu\text{m}$	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye. NMT 6000 particles of $10 \mu\text{m}$ NMT 600 particles of $25 \mu\text{m}$	Complies
8.	Sterility	Should be complies	Complies
9.	Assay:		

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Each ml contains:		
Levetiracetam IP 100 mg	90.0 mg to 180.0 mg (90.0 % to 110.0 %)	100.25 mg 100.25%

Remark: The sample is complies as per ~~IP /BP/ USP/ H~~ specification.

	Prepared By	Checked By	Approved By
Sign/Date		 25/07/2024	 25/07/2024
Name	Vibran Jeet	Bhupinder Navet	Nitish Kumar
Designation	Executive Q.C	Head - QC	Head - QA