

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	LEVECAN (Levetiracetam Injection USP 100 mg/ml)		
Batch No.	24VJ047A	A.R. No.	FP240078
Batch Size	6000 Vial	Sample Quantity	60 NOS
Mfg. Date	10/2024	Date of Testing	21/10/2024
Exp. Date	09/2026	Date of Release	05/11/2024
Reference Batch No	24VJ047	MFG. Lic. No.	N-MB-2023/263

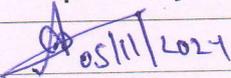
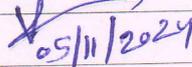
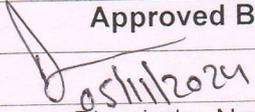
Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid.	Clear and colorless liquid.
2.	Identification (By HPLC)	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Complies
3.	pH	Between 5.0 to 6.0	5.40
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.	Sterility	Should be complies	Complies
8.	Particulate Matter (Visible Particles) (Sub Visible Particles) Particles of $\geq 10 \mu\text{m}$	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 $10 \mu\text{m}$	Complies

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	Particles of $\geq 25 \mu\text{m}$	NMT 600 particles of $25 \mu\text{m}$	
9.	Assay: Each ml contains: Levetiracetam IP 100 mg	90.0 mg to 180.0 mg (90.0 % to 110.0 %)	102.04mg 102.04 %

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

	Prepared By	Checked By	Approved By
Sign/Date	 05/11/2024	 05/11/2024	 05/11/2024
Name	Abhay Mishra	Vikram Jeet	Bhupinder Navet
Designation	Sr. officer QC	Executive-QC	Head-QC