

## CERTIFICATE OF FINISH PRODUCT ANALYSIS

<b>Product Name:</b>	<b>LEVECAN (Levetiracetam Injection USP 100 mg/ml)</b>		
<b>Batch No.</b>	24VJ043C	<b>A.R. No.</b>	FP240069
<b>Batch Size</b>	5000 Vial	<b>Sample Quantity</b>	20 NOS
<b>Mfg. Date</b>	10/2024	<b>Date of Testing</b>	07/10/2024
<b>Exp. Date</b>	09/2026	<b>Date of Release</b>	18/10/2024
<b>Reference Batch No</b>	24VJ043	<b>MFG. Lic. No.</b>	N-MB-2023/263

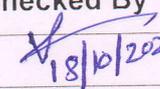
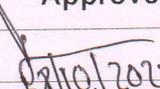
Sr. No.	Test	Specification	Observation
1.	<b>Description</b>	Clear and colorless liquid.	Clear and colorless liquid.
2.	<b>Identification (By HPLC)</b>	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Complies
3.	<b>pH</b>	Between 5.0 to 6.0	5.48
4.	<b>Organic Impurities</b> Levetiracetam acid Any other Impurity Total Impurity	NMT 0.3% NMT 0.1% NMT 1.0%	Complies Complies Complies
5.	<b>Extractable Volume</b>	NLT 5.0 ml	5.0 ml
6.	<b>Bacterial Endotoxins</b>	NMT 0.175 USP Endotoxin Units/mg of levetiracetam	Less than 0.175 USP Endotoxin Units/mg of levetiracetam
7.	<b>Sterility</b>	Should be complies	Complies
8.	<b>Particulate Matter (Visible Particles)</b>  <b>(Sub Visible Particles)</b> 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.	<b>Assay:</b> <b>Each ml contains:</b> <b>Levetiracetam IP 100 mg</b>	90.0 mg to 180.0 mg (90.0 % to 110.0 %)	103.19mg 103.19 %

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

	<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Sign/Date</b>	 18/10/2024	 18/10/2024	 18/10/2024
<b>Name</b>	Abhay Mishra	Vikram Jeet	Bhupinder Navet
<b>Designation</b>	Sr. officer QC	Executive-QC	Head-QC