Pacebiotech Pharma (India) Pvt. Ltd.
Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

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 ≥10 µm	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 µm	Complies

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	Particles of ≥25 µm	NMT 600 particles of 25 µm	
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