



American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Levecan 5 ml Injection (Levetiracetam Injection USP 100 mg/ml)		
Batch No.	26AR040	A.R. No.	AFP260046
Batch Size	50200 AMPS	Sample Quantity	60 Nos
Mfg. Date	03/2026	Date of Testing	04/04/2026
Exp. Date	02/2028	Date of Release	20/04/2026
Reference Batch No	26AR040	MFG. Lic. No.	HP-MB-LL-00235

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	5.54
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 $\geq 10 \mu\text{m}$	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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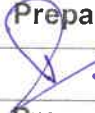
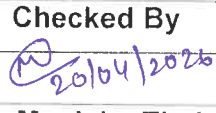

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	Particles of $\geq 25 \mu\text{m}$	NMT 600 particles of $25 \mu\text{m}$	
8.	Sterility	Should be Sterile	Sterile
9.	Assay: Each ml contains: Levetiracetam IP 100 mg	90.0 mg to 110.0 mg (90.0 % to 110.0 %)	100.20 mg 100.20 %

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

	Prepared By	Checked By	Approved By
Sign/Date	 20/04/2026	 20/04/2026	 20/04/2026
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

