



## 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 Injection (Levetiracetam Injection USP 100 mg/ml) |                 |                |
| Batch No.          | 26AR083                                                   | A.R. No.        | AFP260095      |
| Batch Size         | 50980 AMPS                                                | Sample Quantity | 60 Nos         |
| Mfg. Date          | 07/2026                                                   | Date of Testing | 09/08/2026     |
| Exp. Date          | 06/2028                                                   | Date of Release | 24/08/2026     |
| Reference Batch No | 26AR083                                                   | MFG. Lic. No.   | HP-MB-LL-00235 |

| Sr. No. | Test                                                                                                           | Specification                                                                                                                                                                                                                                   | Observation                                             |
|---------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| 1.      | Description                                                                                                    | Clear and colorless liquid.                                                                                                                                                                                                                     | Clear and colorless liquid.                             |
| 2.      | Identification<br>(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                                                                                                                                                                                                                              | 5.48                                                    |
| 4.      | Organic Impurities<br>Levetiracetam acid<br>Any other Impurity<br>Total Impurity                               | NMT 0.3%<br>NMT 0.1%<br>NMT 1.0%                                                                                                                                                                                                                | Complies<br>Complies<br>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<br>(Visible Particles)<br><br>(Sub Visible Particles)<br>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.<br><br>NMT 6000 particles of $10 \mu\text{m}$ | Complies                                                |



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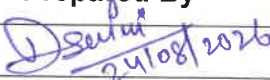
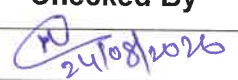
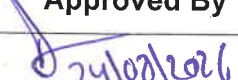
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|    |                                                                             |                                            |                       |
|----|-----------------------------------------------------------------------------|--------------------------------------------|-----------------------|
|    | Particles of $\geq 25 \mu\text{m}$                                          | NMT 600 particles of $25 \mu\text{m}$      |                       |
| 8. | <b>Sterility</b>                                                            | Should be Sterile                          | Sterile               |
| 9. | <b>Assay:</b><br><b>Each ml contains:</b><br><b>Levetiracetam IP 100 mg</b> | 90.0 mg to 110.0 mg<br>(90.0 % to 110.0 %) | 101.80 mg<br>101.80 % |

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

|             |                                                                                                   |                                                                                                    |                                                                                                     |
|-------------|---------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
|             | <b>Prepared By</b>                                                                                | <b>Checked By</b>                                                                                  | <b>Approved By</b>                                                                                  |
| Sign/Date   | <br>24/08/2026 | <br>24/08/2026 | <br>24/08/2026 |
| Name        | Diksha Saini                                                                                      | Manisha Thakur                                                                                     | Bhupinder Navet                                                                                     |
| Designation | Officer QC                                                                                        | Executive-QC                                                                                       | Head-QC                                                                                             |

Name: Bhupinder Navet  
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