



**RENOWED LIFE SCIENCES**  
**PLOT NO-10,11 SEC-6B, I.I.E, SIDCUL HARIDWAR-249403**

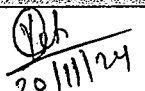
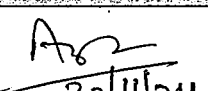
**Certificate OF ANALYSIS**

(See Rule 150 E (F) Under The drug & Cosmetic Act 1940 & Rules thereunder)  
**FINISHED PRODUCT**

|               |                           |              |                     |
|---------------|---------------------------|--------------|---------------------|
| Product Name  | Bacloheal-25              | Ref. No      | TRS/1124/DT410070 F |
| Generic Name  | Baclofen Tablets IP 25 mg |              |                     |
| Batch No.     | DT410070                  | AR. No.      | FP-1750/24          |
| Batch Size    | 4.0 Lac                   | Mfg. Date    | 10/2024             |
| Sample Date   | 14/11/2024                | Exp. Date    | 09/2026             |
| Analysis Date | 29/11/2024                | Release Date | 30/11/2024          |

| Sr.No | Test                                                        | Specification                                                                                                                                                                                                                                                                                                                      | Result                               |
|-------|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| 1.    | Description                                                 | White round biconvex uncoated tablet                                                                                                                                                                                                                                                                                               | White round biconvex uncoated tablet |
| 2.    | Identification<br>A) BY TLC<br><br>B) By assay              | The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram Obtained with the reference solution.<br><br>In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. | Complies<br><br>Complies             |
| 3.    | Average weight                                              | 180 mg $\pm 7.5\%$                                                                                                                                                                                                                                                                                                                 | 179.94 mg                            |
| 4.    | Uniformity of Average weight                                | $\pm 7.5\%$ of average weight                                                                                                                                                                                                                                                                                                      | -2.61% to +2.37%                     |
| 5.    | Dissolution                                                 | (Q) NLT-70%                                                                                                                                                                                                                                                                                                                        | 84.91% to 99.10%                     |
| 6.    | Lactam Impurity                                             | NMT-2.0%                                                                                                                                                                                                                                                                                                                           | Not Detected                         |
| 7.    | Assay : Each uncoated tablet contains:<br>Baclofen IP 25 mg | 22.50 to 27.50 mg.<br>90.0% to 110.0%                                                                                                                                                                                                                                                                                              | 24.75 mg<br>98.99%                   |

**Conclusion:** The above sample ~~complies/does not comply~~ as per IP/BP/USP/IT specification.

|                                                                                                 |                                                                                                 |                                                                                                   |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Analyzed By/Date                                                                                | Checked By/Date                                                                                 | Approved By/Date                                                                                  |
| <br>30/11/24 | <br>30/11/24 | <br>30/11/24 |