

## 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

<b>Product Name</b>	Bacloheal-10 tablets	Ref. No	TRS/1123/RDBAT23002F
Generic Name	Baclofen Tablets IP 10 mg		
Batch No.	RDBTT23002	AR. No.	FP-0830/23
Batch Size	1.0 Lac	Mfg. Date	11/2023
Sample Date	23/11/2023	Exp. Date	10/2025
Analysis Date	23/11/2023	Release Date	27/11/2023

Sr. No	Test	Specification	Result	
1. Description		White colour round biconvex uncoated tablet having a plain surface on both sides.	White colour round biconvex uncoated tablet having a plain surface on both sides.	
2.	Identification A) BY TLC  B) By assay	The principal sport in the chromatogram obtained with the test solution corresponds to that in the chromatogram Obtained with the reference solution.  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	
3.	Average weight	180 mg±7.5%	178.30 mg	
4.	Uniformity of Average weight	±7.5% of average weight	Complies	
5.	Dimension: Thickness Diameter	3.00 ±0.3 mm 8.00 ±0.2mm	2.96 <i>mm</i> 7.95 mm	
6.	Hardness	NLT-2.0 Kg/cm <sup>2</sup>	2.8 Kg/cm <sup>2</sup>	
7.	Friability	NMT-1.0%	0.28%	
8.	Lactam Impurity	NMT-2.0%	Not detected	
9.	Dissolution	(Q) NLT-70%	91.71%	
10.	Assay: Each Uncoated tablet contains: Baclofen IP 10 mg	9.0 to 11.0 mg	9.93 mg	

Conclusion: The above sample complies/does not complies as per IP/BP/USP/IH specification.

Analyzed By/Date	Checked By/Date	Approved By/Date
CY I I		Jul 123
27/11/23		W-7/11/0

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Page No.: 1 of 1