



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

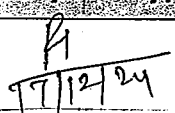
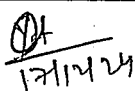
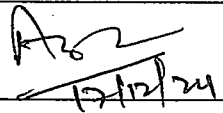
CERTIFICATE OF ANALYSIS

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

Product Name	PREGARICA 50	Ref. No.	TRS/1224/DC412001 F
Generic Name	Pregabalin Capsules IP 50mg		
Batch No.	DC412001	AR. No.	FP-2003/24
Batch Size	1.0 Lac	Mfg. Date	12/2024
Sample Date	11/12/2024	Exp. Date	11/2026
Analysis Date	11/12/2024	Release Date	17/12/2024

Sr.No	Test	Specification	Result
1.	Description	Red colour cap and red colour body hard gelatin capsule, size '2' containing white colour granular powder	Red colour cap and red colour body hard gelatin capsule, size '2' containing white colour granular powder
2.	Identification	Should be comply in assay	Complies
3.	Average weight	330 mg of $\pm 5\%$	328.46 mg
4.	Average filled weight	265 mg of $\pm 5\%$	265.82 mg
5.	Uniformity of weight	$\pm 7.5\%$ of average weight	-2.87% to +2.83%
6.	Dissolution	Q.NLT 70.0%	84.73% to 92.25%
7.	Related substances		
	Lactam	NMT-0.5%	Not Detected
	Lactose Conjugate	NMT-1.5%	Not Detected
	Impurity Peak	NMT-1.0%	Not Detected
8.	Any other secondary Peak	NMT-2.5%	Not Detected
	Sum of all secondary Peak		
8.	Assay: Each hard gelatin capsule contains: Pregabalin IP 50 mg	45.0 mg to 55.0 mg 90.0% to 110.0%	49.43 mg 98.86 %
9.	Microbial Contamination in Nonsterile Product: Total aerobic viable count(TAC) Total Fungal count(TFC) Test for specific microorganisms:- E. coli	NMT- 1000 CFU/gm NMT- 100 CFU/gm Should be absent/gm	20 CFU/gm Less than 10 CFU/gm Absent/gm

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

Analyzed By/Date	Checked By/Date	Approved By/Date
 17/12/24	 17/12/24	 17/12/24