

GALEN PHARMACEUTICAL LTD.

334/5 G.I.D.C.ESTATE, WAGHODIA, .DIST BARODA, Gujarat, India-391760

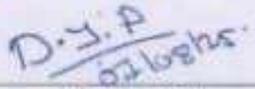
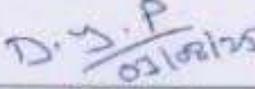
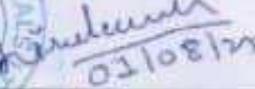
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Generic Name : Diclofenac Sodium suppositories 100 mg	
Product Name : DICLOCAN 100	
Packing : 2X5 Suppositories	Control No. : F/057/25
Batch No. :057	Report No. : F/057/25
Mfg. Date : 06/2025	Test Qty: 60 Suppositories.
Exp. Date : 05/2028	Test: As Per IH Specification.
Batch Size : 1,27,000 Suppositories	Date of receipt : 30/07/2025
Lic No. : G/25A/6163-A	Release Date : 01/08/2025
Storage Conditions: Store protected from light and moisture at a temperature not exceeding 25°C.	

Sr. No.	TEST	RESULT	LIMIT
01	Description	A white colour torpedo shape Suppositories.	A white colour torpedo shape Suppositories.
02	Identification : Uv-vis spectrophotometer	Complies	Should comply as per IH Specification.
03	Wt. of 20 suppositories	22.480 g	22.340 g ($\pm 5\%$)
04	Avg. Wt. of suppository	1.124 g	1.117 g ($\pm 5\%$)
05	Disintegration Time	21 min 35 sec	NMT 60 min.
07	Assay:- Diclofenac Sodium IP	Label : 100 mg Found : 99.81 mg Assay : 99.81%	90.0% to 110.0%

Remarks: The Product conforms as per IH Specification.

Prepared by	Checked by	Approved by
 D. J. P. 02/08/25	 D. J. P. 02/08/25	 D. J. P. 02/08/25
QC Chemist	QC Head	QA Head