

GALEN PHARMACEUTICAL LTD.

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

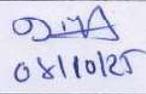
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Generic Name : Diclofenac Sodium suppositories 12.5mg	
Product Name : Diclocan-12.5mg	
Packing: 2X5 Suppositories	Control No. : F/122/25
Batch No. : 122	Report No. : F/122/25
Mfg. Date : 09/2025	Test Qty: 60 Suppositories
Exp. Date : 08/2028	Test: As Per IH Specification.
Batch Size: 102000 Suppositories	Date of receipt : 05/10/2025
Lic No. : G/25A/6163-A	Release Date : 08/10/2025
Storage Conditions: Store in a cool place with temperature below 25°C. Protect it from light.	

Sr. No.	TEST	RESULT	LIMIT
01	Description	A white colour torpedo shaped Suppositories.	A white colour torpedo shaped Suppositories.
02	Identification	Complies	Should comply as per IHS.
03	Wt. of 20 suppositories	22.520 g	22.360 g (±5%)
04	Avg. Wt. of suppository	1.126 g	1.118 g (±5%)
05	Disintegration Time	20 min 39 sec	NMT 60 min
06	Uniformity of Dosage unit	Complies	Should Comply as per IH Specification.
07	Assay:- Diclofenac Sodium BP	Label : 12.5 mg	90.0% to 110.0%
		Found : 12.47 mg	
		Assay : 99.82 %	

Remarks: The Product conforms as per IH Specification.

Prepared by	Checked by		
 08/10/25	 08/10/25		
QC Chemist	QC Head		