

GALEN PHARMACEUTICAL LTD.

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

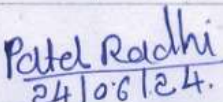
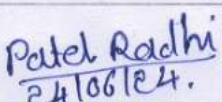
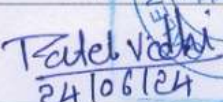
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Generic Name : Diclofenac Sodium suppositories 100 mg	
Product Name : DICLOCAN 100	
Packing: 2X5 Suppositories	Control No. : F/045/24
Batch No. : 045	Report No. : F/045/24
Mfg. Date : 06/2024	Test Qty: 60 Suppositories
Exp. Date : 05/2027	Test: As Per IH Specification.
Batch Size: 1,27,000 Suppositories	Date of receipt : 21/06/2024
Lic No. : G/25/1023	Release Date : 24/06/2024
Storage Conditions: Store protected from light and moisture, at a temperature not exceeding 25°C.	

Sr. No.	TEST	RESULT	LIMIT
01	Description	A white color bullet shape Suppositories.	A white color bullet shape Suppositories.
02	Identification	Complies	Should comply as per IHS.
03	Wt. of 20 suppositories	19.520 g	19.420 g ($\pm 5\%$)
04	Avg. Wt. of suppository	0.976 g	0.971 g ($\pm 5\%$)
05	Disintegration Time	23 min 28 sec	NMT 60 min.
06	Uniformity of Dosage unit	Complies	Should Comply as per In House Specification.
07	Assay:- Diclofenac Sodium IP	Label : 100mg	90.0% to 110.0%
		Found : 99.09 mg	
		Assay : 99.09%	

Remarks: The Product conforms as per In House Specification.

Prepared by	Checked by	Approved by
 24/06/24	 24/06/24	 24/06/24
QC Chemist	QC Head	QA Head

