

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/024/24
Batch No. : 024	Report No. : F/024/24
Mfg. Date : 04/2024	Test Qty: 60 Suppositories.
Exp. Date : 03/2027	Test: As Per BP Specification.
Batch Size : 1,27,000 Suppositories	Date of receipt : 29/04/2024
Lic No. : GUJ/DRUGS/G-1023	Release Date : 02/05/2024
Storage Conditions: Store in well closed containers, below 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 BP Specification.
03	Wt. of 20 suppositories	19.380 g	19.420 g ($\pm 5\%$)
04	Avg. Wt. of suppository	0.969 g	0.971 g ($\pm 5\%$)
05	Disintegration Time	19 min 48 sec	NMT 60 min.
07	Assay:- Diclofenac Sodium IP	Label : 100 mg	90.0% to 110.0%
		Found : 99.34 mg	
		Assay : 99.34 %	

Remarks: The Product conforms as per Specification.

Prepared by <i>Patel Radhi</i> 02/05/24 QC Chemist	Checked by <i>Patel Radhi</i> 21/05/24 QC Head	Approved by <i>Patel Radhi</i> 25/05/24 QA Head
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