

GALEN PHARMACEUTICAL LTD.

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

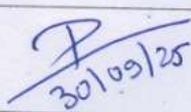
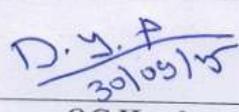
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Generic Name : Bisacodyl Suppositories BP 10 mg	
Product Name : Ducolax	
Packing : 2X5 Suppositories	Control No. : F/126/25
Batch No. : 126	Report No. : F/126/25
Mfg. Date : 09/2025	Test Qty. : 60 Suppositories.
Exp. Date : 08/2028	Test as per : As per BP Specification.
Batch Size : 1,02,000 Suppositories	Date of receipt : 29/09/2025
Lic No. : G/25A/6163-A	Release Date : 30/09/2025
Storage Conditions: Store at a temperature not exceeding 25°C.	

Sr No.	TEST	RESULT	LIMIT
01	Description	A white color Torpedo shape suppositories.	A white color Torpedo shape suppositories.
02	Identification A (By TLC)	Complies	The principal spot in the chromatogram obtained with solution test corresponds to that in the chromatogram obtained with solution reference.
	Identification B (By chemical)	A white precipitate is produce.	A white precipitate is produce.
	Identification C (By chemical)	A reddish violet colour is produced.	A reddish violet colour is produced.
	Identification D (By chemical)	The color becomes Yellowish brown.	The color becomes Yellowish brown.
03	Wt. of 20 suppository	22.320 g	22.220 g ($\pm 5\%$)
04	Avg. Wt. of suppository	1.116 g	1.111 g ($\pm 5\%$)
05	Disintegration Time	21 min 21 sec	NMT 60 min.
06	Related Substances	Complies	Should complies as per BP
07	Bisacodyl BP	Label : 10 mg	90.0% to 110.0%
		Found : 9.987 mg	
		Assay : 99.87 %	

Remarks: The Product conforms to As per BP Specification.

Prepared By:	Checked by:	Approved By:
 30/09/25	 30/09/25	 30/09/25
QC Chemist	QC Head	QA Head