GALEN PHARMACEUTICAL LTD.

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANANLYSIS OF FINISHED PRODUCT

Generic Name: Bisacodyl Suppositories IP 5 mg	
Product Name: Bisacan 5	Control No. :F/007/24
Packing : 2X5 Suppositories	Report No. : F/007/24
Batch No. : 007	Test Packing: 2 X 30 Suppositories.
Mfg. Date : 04/2024	Test Qty. : 60 Suppositories.
Exp. Date : 03/2027	Test as per : As per IP Specification.
Batch Size : 1,02,000 Suppositories	Date of receipt : 26/04/2024
Lic No. : GUJ/DRUGS/G-1023	Release Date : 30/04/2024
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 A (By chemical)	A white precipitate is produced	A white precipitate is produced.
	Identification B (By chemical)	A reddish violet colour is produced.	A reddish violet colour is produced.
	Identification C (By chemical)	The colour becomes yellowish brown.	The colour becomes yellowish brown.
03	Wt. of 20 suppositories	20.180 g	20.000 g (±5%)
04	Avg. Wt. of suppository	1.009g	1.000 g (±5%)
05	Disintegration Time	11 min 60 sec	NMT 60 min.
06	Assay: Bisacodyl IP	Label : 5 mg	
		Found:4.90 mg	
		Assay:98.00%	90.0% to 110.0%

Remarks: The Product conforms to As per IP Specification.

Prepared By:	Checked by:	Approved By:
Pata Radhi 30/04/24	Pata Radhi 30/04/24	Pata Vidhi 30/04/24
QC Chemist	QC Head	QA Head