

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 I.P. 10 mg	
Product Name: Bisacan 10	Control No. : F/085/24
Packing : 2X5 Suppositories	Report No. : F/085/24
Batch No. : 085	Test Packing. : 2 X30 Suppositories
Mfg. Date : 08/2024	Test Qty. : 60 Suppositories.
Exp. Date : 07/2027	Test as per : As per IP Specification.
Batch Size : 1,02,000 Suppositories	Date of receipt : 13/08/2024
Lic No. : G/25/1023	Release Date : 17/08/2024
Storage Conditions: Store 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 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	20.300 g	20.100 g (±5%)
04	Avg. Wt. of suppository	1.015 g	1.005 g (±5%)
05	Disintegration Time	15 min 56 sec	NMT 60 min.
06	Related Substances	Complies	Should complies as per IP
07	Bisacodyl IP	Label : 10 mg	90.0% to 110.0%
		Found : 9.879 mg	
		Assay : 98.79 %	

Remarks: The Product conforms to As per IP Specification.



Prepared By:	Checked by:	Approved By:
<i>Fateh Bhandari</i> 17/08/24	<i>Fateh Bhandari</i> 17/08/24	<i>Fateh Bhandari</i> 17/08/24
QC Chemist	QC Head	QA Head