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: Acetaminophen Suppositories USP 80 mg	
Product Name :**PARACAN 80**	
Packing: 2×5 Suppositories	Control No. : F/103/25
Batch No. : 103	Report No. : F/103/25
Mfg. Date :09/2025	Test Qty. : 60 Suppositories
Exp. Date :08/2028	Test as per: As per USP Specification.
Batch Size : 1,02,000 Suppositories	Date of receipt : 04/10/2025
Lic No. : G/25A/6163-A	Release Date : 06/10/2025
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 torpedo shape Suppositories.	A White color torpedo shape Suppositories.
02	Identification A	Complies	Obtained as per Assay.
	Identification B	Complies	Should Comply as per USP.
03	Wt. of 20 Suppositories	22.180 g	22.00 gm (±5%)
04	Avg. Wt. of suppository	1.109 g	1.100 gm (±5%)
05	Disintegration Time	16 min 25 sec	NMT 60 min.
06	Uniformity of Dosage unit	Complies	Should Comply as per USP.
07	Paracetamol IP	Label : 80 mg	
		Found: 79.928 mg	
		Assay : 99.91 %	90.0% to 110.0%
08	Microbial contamination	Total Aerobic microbial count: 29cfu/g	NMT 1000cfu/g
		Total yeast& moulds count: 08 cfu/g	NMT 100cfu/g
09	Pathogen	Absent	Salmonella: (Should Absent)
		Absent	E coli: (Should Absent)

Remarks: The product complies as per USP Specification.

Prepared By:	Checked by:	Approved By:
06/10/25	06/10/25	06/10/25
QC Chemist	QC Head	QA Head