

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 170 mg	
Product Name : PARACAN 170	
Packing: 2x5 Suppositories	Control No. : F/028/24
Batch No. :028	Report No. : F/028/24
Mfg. Date :05/2024	Test Qty. : 60 Suppositories
Exp. Date :04/2027	Test as per: As per USP Specification.
Batch Size : 1,02,000 Suppositories	Date of receipt : 17/06/2024
Lic No. : GUJ/DRUGS/G-1023	Release Date : 19/06/2024
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	Complies	Obtained as per Assay.
	Identification B	Complies	Should Comply as per USP.
03	Wt. of 20 Suppositories	20.360 g	20.240 gm ($\pm 5\%$)
04	Avg. Wt. of suppository	1.018g	1.012 gm ($\pm 5\%$)
05	Disintegration Time	22 min 59 sec	NMT 60 min.
06	Uniformity of Dosage unit	Complies	Should Comply as per USP.
07	Assay : Acetaminophen	Label : 170 mg	90.0% to 110.0%
		Found: 168.895 mg	
		Assay :99.35%	
08	Microbial contamination	Total Aerobic microbial count: 19 cfu/g	NMT 1000cfu/g
		Total yeast & moulds count: 09 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:
<u>Patan Rader</u> 19/06/24 QC Chemist	<u>Patan Rader</u> 19/06/24 QC Head	<u>Patan Rader</u> 19/06/24 QA Head

