

# GALEN PHARMACEUTICAL LTD.

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

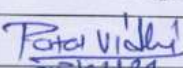
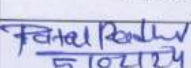
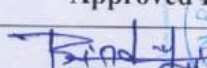
## QUALITY CONTROL DEPARTMENT

### CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Generic Name : Acetaminophen Suppositories USP 125 mg	
Product Name : <b>PARACAN 125</b>	
Packing : 2×5 Suppositories	Control No. : F/209/23
Batch No. : 209	Report No. : F/209/23
Mfg. Date : 01/2024	Test Qty. : 60 Suppositories
Exp. Date : 12/2026	Test as per: As per USP Specification.
Batch Size : 1,02,000 Suppositories	Date of receipt : 02/02/2024
Lic No. : GUJ/DRUGS/G-1023	Release Date : 05/02/2024
Storage Conditions: Store protected from light and moisture, at a temperature not exceeding 25°C.	

Sr. No.	TEST	RESULT	LIMIT
01	Description	A White colour torpedo shape Suppositories.	A White colour torpedo shape Suppositories.
02	Identification A	Complies	Obtained as per Assay.
	Identification B	Complies	Should Comply as per USP.
03	Wt. of 20 Suppositories	20.000 g	20.100 gm (±5%)
04	Avg. Wt. of suppository	1.000 g	1.005 gm (±5%)
05	Disintegration Time	23 min 20 sec	NMT 60 min.
06	Uniformity of Dosage unit	Complies	Should Comply as per USP.
07	Paracetamol IP	Label : 125 mg	90.0% to 110.0%
		Found: 123.28 mg	
		Assay : 98.63 %	
08	Microbial contamination	Total Aerobic microbial count: 23cfu/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.

<b>Prepared By:</b>  05/02/24 QC Chemist	<b>Checked by:</b>  05/02/24 QC Head	<b>Approved By:</b>  05/02/24 QA Head
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