

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

"A/C of American Remedies Healthcare Pvt. Ltd."

Generic Name : Acetaminophen Suppositories USP 125 mg	
Product Name : PARACAN 125	
Packing : 2x5 Suppositories	Control No. : F/158/24
Batch No. : 158	Report No. : F/158/24
Mfg. Date : 11/2024	Test Qty. : 60 Suppositories
Exp. Date : 10/2027	Test as per: As per USP Specification.
Batch Size : 1,02,000 Suppositories	Date of receipt : 27/11/2024
Lic No. : G/25A/6163-A	Release Date : 03/12/2024
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	22.460 g	22.440 gm ($\pm 5\%$)
04	Avg. Wt. of suppository	1.123 g	1.122 gm ($\pm 5\%$)
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: 124.125 mg	
		Assay : 99.30 %	
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.

Prepared By:	Checked by:	Approved By:
<u>S. Roy</u> 03/12/24	<u>S. Roy</u> 03/12/24	
QC Chemist	QC Head	QA Head