

GALEN PHARMACEUTICAL LTD.

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

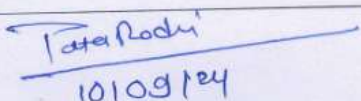
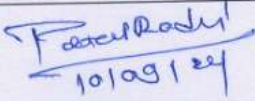

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Generic Name : Glycerin Suppositories USP 2 gm.	
Product Name : AMERICANO GLYCERIN 2	Control No. : F/061/24
Packing : 2X5 Suppositories.	Report No. : F/061/24
Batch No. 061	Test Packing : 2 X 30 Suppositories.
Mfg. Date : 07/2024	Test Qty. : 60 Suppositories.
Exp. Date : 06/2027	Test as per : As per USP Specification.
Batch Size : 52,000 Suppositories.	Date of receipt : 07/09/2024
Lic No. : G/25/1023	Release Date : 10/09/2024
Storage : Store protected from light and moisture at a temperature not exceeding 2°C to 8°C.	

Sr No.	TEST	RESULT	LIMIT
01	Description	A light opaque colour bullet shape suppositories.	A light opaque colour bullet shape suppositories.
02	Identification: (By chemical test).	Complies.	The pink color disappears & when heated pink color reappears.
03	Wt. of 20 suppositories.	40.020 gm	40.000 gm ($\pm 5\%$)
04	Av. Wt. of suppositories.	2.001 gm	2.000 gm ($\pm 5\%$)
05	Water	5.36 %	NMT 15%
06	Each suppository contains: Glycerin I.P 75% w/w	Label: 75.0% w/w Found: 64.822 % w/w Assay : 86.43 % w/w	75 % w/w to 90 % w/w

Remarks: The Product conforms to as per USP Specification.

Prepared By:	Checked by:	Approved By:
 10/09/24	 10/09/24	 10/09/24
QC Chemist	QC Head	QA Head

