

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 1 gm	
Product Name: AMERICANO GLYCERIN I	Control No. : F/060/24
Packing : 2X5suppositories	Report No. : F/060/24
Batch No. 060	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 : 64700 Suppositories.	Date of receipt : 23/09/2024
Lic No. : GUJ/DRUGS/G-1023	Release Date : 26/09/2024
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 Semi transparent bullet shape suppositories.	A Semi transparent bullet shape suppositories.
02	Identification (A) By chemical test.	Complies	The pink color disappears & when heated pink color reappears.
	Identification (B) By IR	Complies	Should comply as per USP.
03	Wt. of 20 suppositories.	20.160 gm	20.000 gm ($\pm 5\%$)
04	Av. Wt. of suppositories.	1.008 gm	1.000 gm ($\pm 5\%$)
05	Water	5.53%	NMT 15%
06	Each suppository contains: Glycerin I.P 75% w/w	Assay : 88.35 % w/w	75%w/w to 90%w/w

Remarks: The Product conforms to as per USP Specification.

Prepared By:	Checked by:	Approved By:
<i>Patel Padhi</i> 20/09/24 QC Chemist	<i>Patel Padhi</i> 26/09/24 QC Head	<i>Patel</i> 26/09/24 QA Head

