

# 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/GS023/24
Packing : 2X5suppositories	Report No. : F/GS023/24
Batch No. GS023	Test Packing : 2 X 30 Suppositories
Mfg. Date : 04/2024	Test Qty. : 60 Suppositories
Exp. Date :03/2027	Test as per : As per USP Specification.
Batch Size : 52,000 Suppositories.	Date of receipt : 19/04/2024
Lic No. : GUJ/DRUGS/G-1023	Release Date : 21/04/2024
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 complies as per USP.
03	Wt. of 20 suppositories.	40.020gm	40.000 gm (±5%)
04	Av. Wt. of suppositories.	2.001gm	2.000 gm (±5%)
05	Water	5.62 %	NMT 15%
06	Each suppository contains: Glycerin I.P 75% w/w	Label: 75.0%w/w	75%w/w to 90%w/w
		Found: 64.61 %w/w	
		Assay : 86.15 % w/w	

Remarks: The Product conforms to as per USP Specification.

Prepared By:	Checked by:	Approved By:
<i>Patel Radhi</i> 21/04/24	<i>Patel Radhi</i> 21/04/24	<i>Patel Radhi</i> 21/04/24
QC Chemist	QC Head	QA Head

