Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur Haridwar-249403, Uttarakhand, INDIA.

QUALITY CONTROL

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name :	HYDROSEAL GEL			
Generic Name :	Amorphous Hydrogel Wound Dre	ssing with Colloida	l Silver	
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC	
Batch No.:	PA2BJ01	A. R. No.:	F20231029061	
Mfg. Date :	Oct. 2023	Pack Size:	1x15 Gm	
Expiry date:	Mar. 2025	Pack Type:	Lami tube (Sale)	
Batch Size :	9667 NOS	Sampled On:	29/10/23	
Product Code:	40064033	Sample Quantity:	12 NOS	
Specification No, Ver No.:	STS/FP/40064033-00	Sampled By:	KAVIRAJ SINGH	
Ref. STP No., Ver No.:	STP/FP/1398	Analyzed By:	PAWAN KUMAR	
Manufactured For:	Healing Pharma India Pvt. Ltd.	Date of Analysis:	30/10/23	
Manufactured By:	Pure & Cure Healthcare Pvt. Ltd.	Analysis Complet	ion Date: 07/11/23	

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	A light brown transparent gel filled in lami tube.	A light brown transparent gel filled in lami tube.
2	Identification	Positive for Colloidal Silver, Propylene Glycol, Triethanolamine & Carbomer.	Complies
3	Average fill weight	Not less than 15.0 g	15.06 g
4	Uniformity of weight	Not less than 90.0% of labelled amount.	100.0% and 100.6%
5	рН	Between 4.5 and 8.5	5.81
6	Microbiological test	As below	As below
a.	Total aerobic count	Not more than 100 cfu/g	Less than 10 cfu /g
b.	Total fungal count	Not more than 10 cfu/g	Less than 10 cfu /g

	Prepared By QC	Reviewed By QC	Approved By QC
Date	07/11/23	07/11/23	07/11/23
Name	SACHIN KUMAR SHARMA	NAVEEN	RAJESHWAR SINGH
Designation	ASST. OPERATOR	ASST. MANAGER	DY. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name: NITIN KUMAR; Date: 07/11/2023

FORMAT No.: HQC-008/F05-04 Page 01 of 04

Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur Haridwar-249403, Uttarakhand, INDIA.

QUALITY CONTROL

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name:	HYDROSEAL GEL			
Generic Name :	Amorphous Hydrogel Wound Dre	ssing with Colloida	l Silver	
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC	
Batch No.:	PA2BJ01	A. R. No.:	F20231029061	
Mfg. Date :	Oct. 2023	Pack Size:	1x15 Gm	
Expiry date:	Mar. 2025	Pack Type:	Lami tube (Sale)	
Batch Size :	9667 NOS	Sampled On:	29/10/23	
Product Code:	40064033	Sample Quantity:	12 NOS	
Specification No, Ver No.:	STS/FP/40064033-00	Sampled By:	KAVIRAJ SINGH	
Ref. STP No., Ver No.:	STP/FP/1398	Analyzed By:	PAWAN KUMAR	
Manufactured For:	Healing Pharma India Pvt. Ltd.	Date of Analysis:	30/10/23	
Manufactured By:	Pure & Cure Healthcare Pvt. Ltd.	Analysis Complet	ion Date: 07/11/23	

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
c.	Pathogens	As below		As below
c.1	Pseudomonas aeruginosa	Should be absent /g		Absent/g
c.2	Staphylococcus aureus	Should be absent/g		Absent/g
7	Leakage test	No leakage should be observed.		Complies
8	Assay	Shelf Life Limit	Release Limit	
а.	Colloidal Silver - 32 ppm	NLT 28.80ppm to NMT 40.00ppm	NLT 28.80ppm to NMT 40.00ppm	33.03ppm 103.22%
		(NLT 90.00% to NMT125.00% of label claimed)	(NLT 90.00% to NMT125.00% of label claimed)	

	Prepared By QC	Reviewed By QC	Approved By QC
Date	07/11/23	07/11/23	07/11/23
Name	SACHIN KUMAR SHARMA	NAVEEN	RAJESHWAR SINGH
Designation	ASST. OPERATOR	ASST. MANAGER	DY. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name: NITIN KUMAR; Date: 07/11/2023

FORMAT No.: HQC-008/F05-04 Page 02 of 04

Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur Haridwar-249403, Uttarakhand, INDIA.

QUALITY CONTROL

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name:	HYDROSEAL GEL			
Generic Name :	Amorphous Hydrogel Wound Dre	ssing with Colloida	l Silver	
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC	
Batch No.:	PA2BJ01	A. R. No.:	F20231029061	
Mfg. Date :	Oct. 2023	Pack Size:	1x15 Gm	
Expiry date:	Mar. 2025	Pack Type:	Lami tube (Sale)	
Batch Size :	9667 NOS	Sampled On:	29/10/23	
Product Code:	40064033	Sample Quantity:	12 NOS	
Specification No, Ver No.:	STS/FP/40064033-00	Sampled By:	KAVIRAJ SINGH	
Ref. STP No., Ver No.:	STP/FP/1398	Analyzed By:	PAWAN KUMAR	
Manufactured For:	Healing Pharma India Pvt. Ltd.	Date of Analysis:	30/10/23	
Manufactured By:	Pure & Cure Healthcare Pvt. Ltd.	Analysis Complet	ion Date: 07/11/23	

S.No.	TEST	ACCEPTANC	E CRITERIA	RESULTS
b.	Propylene Glycol IP - 4.96 %w/w	NLT 4.46% w/w to NMT 5.46% w/w (NLT 90.00% to NMT110.00% of label claimed)	NLT 4.46% w/w to NMT 5.46% w/w (NLT 90.00% to NMT110.00% of label claimed)	4.95% w/w 99.80%
c.	Triethanolamine BP - 0.32 %w/w	NLT 0.288% w/w to NMT 0.352% w/w (NLT 90.00% to NMT110.00% of label claimed)	NLT 0.288% w/w to NMT 0.352% w/w (NLT 90.00% to NMT110.00% of label claimed)	0.318% w/w 99.38%

	Prepared By QC	Reviewed By QC	Approved By QC
Date	07/11/23	07/11/23	07/11/23
Name	SACHIN KUMAR SHARMA	NAVEEN	RAJESHWAR SINGH
Designation	ASST. OPERATOR	ASST. MANAGER	DY. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name: NITIN KUMAR; Date: 07/11/2023

FORMAT No.: HQC-008/F05-04 Page 03 of 04

Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur Haridwar-249403, Uttarakhand, INDIA.

QUALITY CONTROL

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name:	HYDROSEAL GEL			
Generic Name :	Amorphous Hydrogel Wound Dre	ssing with Colloida	l Silver	
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC	
Batch No. :	PA2BJ01	A. R. No.:	F20231029061	
Mfg. Date :	Oct. 2023	Pack Size:	1x15 Gm	
Expiry date:	Mar. 2025	Pack Type:	Lami tube (Sale)	
Batch Size :	9667 NOS	Sampled On:	29/10/23	
Product Code:	40064033	Sample Quantity:	12 NOS	
Specification No, Ver No.:	STS/FP/40064033-00	Sampled By:	KAVIRAJ SINGH	
Ref. STP No., Ver No.:	STP/FP/1398	Analyzed By:	PAWAN KUMAR	
Manufactured For:	Healing Pharma India Pvt. Ltd.	Date of Analysis:	30/10/23	
Manufactured By:	Pure & Cure Healthcare Pvt. Ltd.	Analysis Complet	ion Date: 07/11/23	

S.No.	TEST	ACCEPTANCI	E CRITERIA	RESULTS
d.	Carbomer IP - 0.76 %	NLT 0.684% w/w	NLT 0.684% w/w	0.749% w/w
	w/w	to NMT 0.836%	to NMT 0.836%	98.55%
		w/w	w/w	
		(NLT 90.00% to NMT110.00% of	(NLT 90.00% to NMT110.00% of	
		label claimed)	label claimed)	

CONCLUSION: The Finished Product complies as per IH Specifications.

	Prepared By QC	Reviewed By QC	Approved By QC
Date	07/11/23	07/11/23	07/11/23
Name	SACHIN KUMAR SHARMA	NAVEEN	RAJESHWAR SINGH
Designation	ASST. OPERATOR	ASST. MANAGER	DY. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED
Name: NITIN KUMAR; Date: 07/11/2023

FORMAT No.: HQC-008/F05-04 Page 04 of 04