

Pure & Cure Healthcare Pvt. Ltd.

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

QUALITY CONTROL**CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HYDROBROOK GEL		
Generic Name :	Amorphous Hydrogel Wound Dressing with Colloidal Silver		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PA2BK02	A. R. No.:	F20240727083
Mfg. Date :	Jul. 2024	Pack Size:	1x15 Gm
Expiry date:	Jun. 2026	Pack Type:	Seamless tube (sale)
Batch Size :	10000 NOS	Sampled On:	27/07/24
Product Code :	40067081	Sample Quantity:	12 NOS
Specification No, Ver No.:	STS/FP/40067081-00	Sampled By:	IRFAN ANSARI
Ref. STP No. , Ver No.:	STP/FP/1398	Analyzed By:	DEEPA
Manufactured For :	Healing Pharma	Date of Analysis:	28/07/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	05/08/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	A light brown transparent gel filled in seamless tube.	A light brown transparent gel filled in seamless tube.
2	Identification	Positive for Colloidal Silver, Propylene Glycol, Triethanolamine & Carbomer.	Complies
3	Average fill weight	Not less than 15.0 g	15.07 g
4	Uniformity of weight	Not less than 90.0% of labelled amount.	100.00% and 100.66%
5	pH	Between 4.5 and 8.5	5.09
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	05/08/24	05/08/24	05/08/24
Name	ROBIN KUMAR	SHRAVAN	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 : 05/08/2024

Pure & Cure Healthcare Pvt. Ltd.

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

QUALITY CONTROL**CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HYDROBROOK GEL		
Generic Name :	Amorphous Hydrogel Wound Dressing with Colloidal Silver		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PA2BK02	A. R. No.:	F20240727083
Mfg. Date :	Jul. 2024	Pack Size:	1x15 Gm
Expiry date:	Jun. 2026	Pack Type:	Seamless tube (sale)
Batch Size :	10000 NOS	Sampled On:	27/07/24
Product Code :	40067081	Sample Quantity:	12 NOS
Specification No, Ver No.:	STS/FP/40067081-00	Sampled By:	IRFAN ANSARI
Ref. STP No. , Ver No.:	STP/FP/1398	Analyzed By:	DEEPA
Manufactured For :	Healing Pharma	Date of Analysis:	28/07/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	05/08/24

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	
a.	Colloidal Silver - 32 ppm	NLT 28.80ppm to NMT 40.00ppm (NLT 90.00% to NMT 125.00% of label claimed)	NLT 28.80ppm to NMT 40.00ppm (NLT 90.00% to NMT 125.00% of label claimed)	31.56ppm 98.63%

	Prepared By QC	Reviewed By QC	Approved By QC
Date	05/08/24	05/08/24	05/08/24
Name	ROBIN KUMAR	SHRAVAN	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 : 05/08/2024

Pure & Cure Healthcare Pvt. Ltd.Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur
Haridwar-249403, Uttarakhand, INDIA.**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HYDROBROOK GEL		
Generic Name :	Amorphous Hydrogel Wound Dressing with Colloidal Silver		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PA2BK02	A. R. No.:	F20240727083
Mfg. Date :	Jul. 2024	Pack Size:	1x15 Gm
Expiry date:	Jun. 2026	Pack Type:	Seamless tube (sale)
Batch Size :	10000 NOS	Sampled On:	27/07/24
Product Code :	40067081	Sample Quantity:	12 NOS
Specification No, Ver No.:	STS/FP/40067081-00	Sampled By:	IRFAN ANSARI
Ref. STP No. , Ver No.:	STP/FP/1398	Analyzed By:	DEEPA
Manufactured For :	Healing Pharma	Date of Analysis:	28/07/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	05/08/24

S.No.	TEST	ACCEPTANCE 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)	0.321%w/w 100.31%

	Prepared By QC	Reviewed By QC	Approved By QC
Date	05/08/24	05/08/24	05/08/24
Name	ROBIN KUMAR	SHRAVAN	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 : 05/08/2024

Pure & Cure Healthcare Pvt. Ltd.

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

QUALITY CONTROL**CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HYDROBROOK GEL		
Generic Name :	Amorphous Hydrogel Wound Dressing with Colloidal Silver		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PA2BK02	A. R. No.:	F20240727083
Mfg. Date :	Jul. 2024	Pack Size:	1x15 Gm
Expiry date:	Jun. 2026	Pack Type:	Seamless tube (sale)
Batch Size :	10000 NOS	Sampled On:	27/07/24
Product Code :	40067081	Sample Quantity:	12 NOS
Specification No, Ver No.:	STS/FP/40067081-00	Sampled By:	IRFAN ANSARI
Ref. STP No. , Ver No.:	STP/FP/1398	Analyzed By:	DEEPA
Manufactured For :	Healing Pharma	Date of Analysis:	28/07/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	05/08/24

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
d.	Carbomer IP - 0.76 % w/w	NLT 0.684%w/w to NMT 0.836% w/w (NLT 90.00% to NMT110.00% of label claimed)	NLT 0.684%w/w to NMT 0.836% w/w (NLT 90.00% to NMT110.00% of label claimed)	0.757%w/w 99.61%

CONCLUSION : The Finished Product complies as per IH Specifications.

	Prepared By QC	Reviewed By QC	Approved By QC
Date	05/08/24	05/08/24	05/08/24
Name	ROBIN KUMAR	SHRAVAN	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 : 05/08/2024