

**AKUMS DRUGS & PHARMACEUTICALS LTD.**47, Sector-6A, I.I.E., SIDCUL, Ranipur
Haridwar-249403, Uttarakhand , INDIA**QUALITY CONTROL****CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Product Name :	SCARHEAL GEL 1X15GM		
Generic Name :	Allium Cepa Extract , Heparin Sodium and Allantoin Gel		
Mfg. Lic. No. :	16/UA/2010	Market:	DOMESTIC
Batch No. :	HYAA07	A. R. No.:	F20240831007
Mfg. Date :	08/2024	Pack Size:	15 gm
Expiry date:	07/2026	Pack Type:	Lami tube
Batch Size :	13000 NOS	Sampled On:	31/08/24
Product Code :	40035833	Sample Quantity:	10 NOS
Specification No, Ver No.:	STS/FP/40035833-00	Sampled By:	Dinesh
Ref. STP No. , Ver No.:	STP/FP/40035833-00	Analyzed By:	BHAVNA
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	31/08/24
Manufactured By :	Akums Drugs And Pharmaceuticals Ltd. Plant-5	Analysis Completion Date:	11/09/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Pale yellow to brownish opaque gel with mild fragrance filled in Lami tube.	Brownish opaque gel with mild fragrance filled in Lami tube.
2	Consistency	Should be Homogeneous gel and free from lumps.	Homogeneous gel and free from lumps.
3	Foreign matter	Should be free from foreign matter .	Free from foreign matter .
4	Identification	Should be Positive for Allium cepa, Heparin Sodium & Allantoin as per Assay.	Positive for Allium cepa, Heparin Sodium & Allantoin as per Assay.
5	pH	Between 4.00 and 6.00	4.45
6	Average Net Weight	Not less than 15.00 gm.	15.12

	Prepared By QC	Reviewed By QC	Approved By QC
Date	11/09/24	11/09/24	11/09/24
Name	BHAVNA	PRADEEP KR. SHARMA	KAPIL KUMAR SINGH
Designation	ASST.EXECUTIVE	SR. EXECUTIVE	MANAGER

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

QA REVIEWED

Name : SUMIT KUMAR AGARWAL ; Date : 11/09/2024

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
7	Uniformity of weight	Between 91.00% and 109.00% of Labelled Amount.	Between 100.00% to 101.33%
8	Microbial count	As below	As below
(A)	Total aerobic microbial count	Not more than 1000 cfu/gm	20 cfu/gm
(B)	Total Yeast & Mould Count	Not more than 10 cfu/gm	Less than 10 cfu/gm
(C)	Pathogens	As below	As below
(i)	Escherichia coli	Should be Absent.	Absent/g
(ii)	Salmonellae	Should be absent/10g	Absent/10g
(iii)	Pseudomonas aeruginosa	Should be absent.	Absent/g

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
(iv)	Staphylococcus aureus	Should be absent.		Absent/g
9	Assay - Each g Contains	Shelf Life Limit	Release Limit	
a)	Allium Cepa Extract - 0.1 gm	NLT 0.09000gm to NMT 0.11000gm (NLT 90.00% to NMT110.00% of label claimed)	NLT 0.09500gm to NMT 0.11000gm (NLT 95.00% to NMT110.00% of label claimed)	0.10057gm 100.57%

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
b)	Heparin Sodium IP - 50 IU	NLT 45.00IU to NMT 55.00IU (NLT 90.00% to NMT110.00% of label claimed)	NLT 47.50IU to NMT 55.00IU (NLT 95.00% to NMT110.00% of label claimed)	51.52IU 103.04%
c)	Allantoin IP - 0.01 gm	NLT 0.009000gm to NMT 0.011000gm (NLT 90.00% to NMT110.00% of label claimed)	NLT 0.009500gm to NMT 0.011000gm (NLT 95.00% to NMT110.00% of label claimed)	0.009938gm 99.38%

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CONCLUSION : The Finished Product complies as per IH Specifications.

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