

**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 :	LULICONAZ-S CREAM 1X15 GM		
Generic Name :	Luliconazole and Salicylic Acid Cream.		
Mfg. Lic. No. :	16/UA/2010	Market:	DOMESTIC
Batch No. :	HYAB07	A. R. No.:	F20240319001
Mfg. Date :	03/2024	Pack Size:	15 gm
Expiry date:	02/2026	Pack Type:	Lami tube
Batch Size :	20000 NOS	Sampled On:	19/03/24
Product Code :	40057128	Sample Quantity:	12 NOS
Specification No, Ver No.:	STS/FP/40057128-00	Sampled By:	Dinesh
Ref. STP No. , Ver No.:	STP/FP/40057128-00	Analyzed By:	SHWETA SINGH
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	19/03/24
Manufactured By :	Akums Drugs And Pharmaceuticals Ltd. Plant-5	Analysis Completion Date:	26/03/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White coloured viscous cream filled in Lami tube.	White coloured viscous cream filled in Lami tube.
2	Identification (By HPLC)	As below	As below
A	Luliconazole	In the assay, the retention time of the major peaks obtained with the test solution correspond to the retention time of major peaks obtained with the standard solution.	In the assay, the retention time of the major peaks obtained with the test solution correspond to the retention time of major peaks obtained with the standard solution.

	Prepared By QC	Reviewed By QC	Approved By QC
Date	26/03/24	26/03/24	26/03/24
Name	ROBIN KUMAR	PRADEEP KR. SHARMA	KAPIL KUMAR SINGH
Designation	TRAINEE	SR. EXECUTIVE	MANAGER

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

QA REVIEWED

Name : SUMIT KUMAR AGARWAL ; Date : 27/03/2024

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
B	Salicylic acid	In the assay, the retention time of the major peaks obtained with the test solution correspond to the retention time of major peaks obtained with the standard solution.	In the assay, the retention time of the major peaks obtained with the test solution correspond to the retention time of major peaks obtained with the standard solution.
3	Average fill weight	Not less than 15.00 g	15.15 gm
4	Uniformity of fill Weight	Any single container not less than 90.00% of the Labelled Amount.	Between 100.67% to 101.33%
5	pH	Between 4.5 to 5.5	5.10
6	Viscosity	Between 15000 cps to 25000 cps	21235 cps
7	Heavy Metals	As below	As below
i	Lead (Pb)	Not more than 20 ppm	0.093 ppm

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
ii	Arsenic (as AS ₂ O ₃)	Not more than 2 ppm	Below detected limit
8	Total fatty substance content	Not less than 5.00 %	9.28 %
9	Total Residue	Not less than 10.00 %	22.05 %
10	Microbiological Profile	As below	As below
a)	Total Aerobic Bacterial Count	Not more than 100 cfu/g	10 cfu/g
b)	Total yeast and moulds count	Not more than 10 cfu/g	Less than 10 cfu/g
c)	Pathogens	As below	As below
i)	Escherichia coli	Should be Absent/g	Absent/g

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
ii)	Salmonellae	Should be Absent/10g		Absent/10g
iii)	Pseudomonas aeruginosa	Should be Absent/g		Absent/g
iv)	Staphylococcus aureus	Should be Absent/g		Absent/g
11	Assay	Shelf Life Limit	Release Limit	
A	Luliconazole IP - 1 % w/w	NLT 0.9000%w/w to NMT 1.1000% w/w (NLT 90.00% to NMT110.00% of label claimed)	NLT 0.9500% w/w to NMT 1.0500%w/w (NLT 95.00% to NMT105.00% of label claimed)	1.0093%w/w 100.93%

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
B	Salicylic acid IP - 3 % w/w	NLT 2.7000%w/w to NMT 3.3000% w/w (NLT 90.00% to NMT110.00% of label claimed)	NLT 2.8500% w/w to NMT 3.1500%w/w (NLT 95.00% to NMT105.00% of label claimed)	3.0265%w/w 100.88%

CONCLUSION : The Finished Product complies as per IH Specifications.

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