



UNIZA LIFECARE PRIVATE LIMITED

OLD S.R NO 404,SR.NO 919 KADI-DETROJ ROAD BALASAR KADI - 382715

QUALITY CONTROL DEPARTMENT

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: LULICONAZ 10 GM	A.R. No.	: 7/4/0906
Packing	: 10 Gram	Release Dt.	: 27-11-2024
Generic Name	: Luliconazole Cream IP 1%w/w	T.R. Slip No.	: ULPPTR24250388
		T.R. Slip Dt.	: 18-11-2024
Product Code	: 700237	Mfg. Dt. :	11/24
Batch No.	: 40854A	Exp. Dt. :	10/27
Actual Batch Size	: 201.0000 kg	Test As per :	IP
Sample Size	: 150.000 Gram	Specification No. :	FPS/OIN/0100/00
Released Qty.	: 200.9000 kg	STP No.	: UNF/MOA/0468/00
		Mfg. Lic. No.	: G/25/2489
		Location	: KADI
		Company	: UNIZALIFE

Sr. No.	Test	Result	Specification
1.00	Description	A white colour smooth cream filled in laminated tube.	A white to off white colour smooth cream filled in laminated tube.
2.00	Identification	.	.
2.01	By HPLC	Complies	In the Assay, the chromatogram obtained with standard solution shows a peak with the same retention time as the peak due to Luliconazole in the chromatogram obtained with sample solution
3.00	Minimum filling	10.02 gm	Not less than 10.0 gm.
4.00	Homogeneity: (By Visual)	Complies	No visible particles detected in 3 of 4 sample.
5.00	Leakage test: (At 45°C ±3°C for 8 hrs)	Complies	No cream leakage detected.
6.00	pH	6.7	3.5 to 7.0
7.00	Related Substance: (For Luliconazole S-E form)	.	.
7.01	Luliconazole S-E Form	Not Detected	Not More Than 2.5 %
8.00	Related Substance: (For Luliconazole Z form)	.	.
8.01	Luliconazole Z form	Not Detected	Not more than 0.3 %.
8.02	All other secondary impurity	Not Detected	Not more than 0.3 %.
9.00	Assay	.	.
9.01	Composition	.	.
9.02	Luliconazole IP ...1 % w/w	0.9964% w/w 99.64%	Between 90.0 % to 110.0% of the label claim.
10.00	Microbial Contamination	.	.

Prepared By	Checked By	Approved By
JAYENDRA PATEL	RAKESHBHAI PATEL	MANOJ PATEL
QC EXECUTIVE	ASSIS. MANAGER	QC MANAGER

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Sr. No.	Test	Result	Specification
10.01	Total aerobic microbial count	Less than 10 CFU/g	Not more than 100 CFU/g.
10.02	Total yeast and mould count	Less than 10 CFU/g	Not more than 10 CFU/g.
10.03	E.Coli	Absent	Should be absent
10.04	Salmonella	Absent	Should be absent
10.05	Pseudomonas aeruginosa	Absent	Should be absent
10.06	Staphylococcus aureus	Absent	Should be absent

Conclusion : The above sample complies as per IP. "This computer generated certificate of analysis is valid without signature"

Prepared By	Checked By	Approved By
JAYENDRA PATEL	RAKESHBHAI PATEL	MANOJ PATEL
QC EXECUTIVE	ASSIS. MANAGER	QC MANAGER

Note : "Report is computer generated,does not required signature"

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