

ZEE LABORATORIES

47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. : 252618539

Document No. : 252626041

Ref. STS No.	4832	Product Code	FG04832
Product Name	OINT. FUNGIZEE-T		
Generic Name	ITRACONAZOLE 1% & TERBINAFINE 1% CREAM		
Batch No.	825-395	Date Of Sampling	04/12/2025
Batch Size	4000.000 tube	Sample Quantity	10.000 tube
Mfg. Date	11/2025	Exp. Date	10/2027
A. R. No.	ZL25FG05484	Date Of Release	09/12/2025

S NO.	Tests	Specification	Results
1	Description	A white colour semi solid cream filled in printed lami tube	Complies
2	Identification	Positive for Itraconazole & Terbinafine Hydrochloride	Complies
3	Average weight	NLT 15 gm	15.10 gm
4	Uniformity of weight	Within limit	Complies
5	pH	4.5 - 7.5	6.58
6	Assay: Composition: Itraconazole B.P. 1.0% w/w	NLT 90.0% and NMT 110.0% of labeled amount	98.12 %
7	Terbinafine Hydrochloride I.P. 1.0% w/w	NLT 90.0% and NMT 110.0% of labeled amount	95.23 %
8	Microbial Limit Test:		
9	Total Aerobic microbial count	NMT 100 Cfugm	20 Cfugm
10	Total fungal count	NMT 10 Cfugm	Nil
11	Staphylococcus aureus	Should be absent/gm	Absent
12	Pseudomonas aeruginosa	Should be absent/gm	Absent

Remarks The above sample complies/does not comply with prescribed standards of Quality with respect to above tests as per IP/BP/USP/In house specification.

Particulars	Prepared / Analysed by	Reviewed By	Approved / Authorized By
Signature:	<i>Amj</i>	<i>Q</i>	
Name:	Amal Kumar	Sunil Kothari	Amal Kumar
Designation:	QC Executive	Astt. QCM	QCM
Date	09/12/2025	09/12/2025	09/12/2025