



ZEE LABORATORIES LTD

Behind 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)

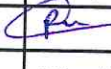
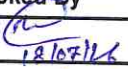
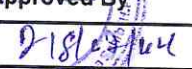
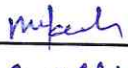
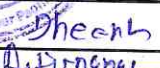
Work Order No. : 262716106

Sample Rec No. : 262717696

QC No. : 262720287

Ref. STS No.	125	Product Code	FG07528
Product Name	CAP. ACTININ-O 10		
Generic Name	ISOTRETINOIN CAPSULES I.P. 10MG		
Batch No.	1626-258	Date Of Sampling	10/07/2026
Batch Size	50000.000 CAP	Sample Quantity	50.000 CAP
Mfg. Date	07/2026	Exp. Date	06/2028
A. R. No.	ZL26FG05203	Date Of Report	18/07/2026
S NO.	Tests	Specification	Results
1	Description	A Red colour, soft gelatin capsule filled with yellow colour semi solid liquid.	Complies
2	Identification	Examine by HPLC: Should be positive for Isotretinoin.	Complies
3	Average Filling	400 mg $\pm$ 7.5%	398.6 mg
4	Uniformity of Filling	Average Filling of Capsules $\pm$ 7.5.0%.	Complies
5	Disintegration Test	Not more than 60 minutes	12:14 Min
6	Dissolution Test	Not Less than 80 % of the stated amount of Isotretinoin	92%
7	Organic Impurities	Should be Complies	Complies
8	Assay Each soft gelatin capsule contains Isotretinoin I.P. 10 mg	NLT 90.0% and NMT 110.0% of the labeled amount	102.3%
9	Uniformity of dose units	Should be Complies to	Complies
10	Microbial Contamination: - Total aerobic Microbial Count	NMT 1000cfu/gm.	30cfu/gm
11	Total Combined Molds and Yeasts count	NMT 100cfu/gm.	<10cfu/gm
12	Pathogen: -Escherichia coli	Should be absent	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	Analysis By	Prepared By	Checked By	Approved By
Sign & Date	 18/07/26	18/07/2026	 18/07/26	 18/07/26
Name:	Priyanka	Mr. Raghuveer		QCM 
Designation:	officer ccc	officer ccc	officer	officer