



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. :

Document No. : 242554726

Ref. STS No.	2541	Product Code	FG03790
Product Name	CAP. ACTININ-O 20		
Generic Name	ISOTRETINOIN SOFT GELATIN CAPSULES I.P. 20MG		
Batch No.	1625-96	Date Of Sampling	24/03/2025
Batch Size	100000.000 CAP	Sample Quantity	50.000 CAP
Mfg. Date	02/2025	Exp. Date	01/2028
A. R. No.	ZL25FG02318	Date Of Release	02/04/2025
S NO.	Tests	Specification	Results
1	Description	A Red colour, soft gelatin capsule filled with yellow colour semi solid liquid.	Complies
2	Identification By hplc	In the test for Related substances, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution.	Complies
3	Identification By U.V	When examined in the range 300 nm to 400 nm. the final solution obtained in the Assay, exhibits a maximum at 356 nm.	Complies
4	Average Filling	300 mg \pm 7.5%	301.2 mg
5	Uniformity of Filling	Not more than two of the individual weights deviate from the Average weight by more than the 7.5% and none deviates by more than 15%.	Complies
6	Disintegration Test	Not more than 60 minutes	12:35 Min
7	Dissolution Test	Q. Not Less Than 85 % of the state amount of Isotretinoin.	92% to 96 %
8	Uniformity of content	NLT 85% to NMT 115% to Average Content.	Complies %
9	Assay Each soft gelatin capsule contains Isotretinoin U.S.P. 20 mg	NLT 90.0% and NMT 110.0% of the labeled amount of Isotretinoin.	101.4 %
10	Related Substances	Tretinoin :NMT 4.0%, The area of any secondary peak: NMT 1.0%, the sum of the area of other secondary peaks: NMT 1.5%	Complies
11	Microbial Contamination: - Total aerobic Microbial Count	NMT 1000cfu/gm.	350 cfu/gm
12	Total Combined Molds and Yeasts count	NMT 100cfu/gm.	<10 cfu/gm
13	Pathogen: -Escherichia coli	Should be absent	absent

Particulars	Prepared By	Checked By	Approved By
Sign & Date	2024/04/2025	2024/04/2025	2024/04/2025
Name:	Rajkumar	Dheshika	Dr. Deep Singh
Designation:	Officer in Charge	Analyst	Analyst





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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 By	Checked By	Approved By
Sign & Date	4/02/04/2025	4/02/04/2025	4/02/04/2025
Name:	Rayhuu	Dheeraj	Thakur Deep Singh
Designation:	Officer in	Authorizing	QCM