

RESTRICTED CIRCULATION

CERTIFICATE OF ANALYSIS

A/C of Healing Pharma Pvt Ltd

PRODUCT NAME	ACCUFINE 5 CAPSULES		
GENERIC NAME	Isotretinoin Capsules IP 5 MG		
BATCH NO.	A52402	A.R. NO.	BF/00457/24
MFG. DATE	07/2024	DATE OF SAMPLING	03/08/2024
EXP. DATE	06/2026	DATE OF RELEASE	08/08//2024
BATCH SIZE	102000 Capsules	FILLED WEIGHT	260 mg
MFG. LIC. NO.	G/25A/5315/-A	SAMPLE QUANTITY	100 Capsules

SR. NO.	TEST	RESULT	SPECIFICATION
1.0	Description	Red coloured oval shaped soft gelatin capsules containing yellowish orange Coloured homogeneous oily paste.	Red coloured oval shaped soft gelatin capsules containing yellowish orange Coloured homogeneous oily paste.
2.0	Disintegration Time	12:10 Min	NMT 30 Minutes at 37°C
3.0	Average Weight Of Content	254.4 mg	260 mg $\pm$ 10 %
4.0	Uniformity Of Weight	Complies	$\pm$ 10 % of Avg. Weight
5.0	Assay		
5.1	Isotretinoin 5 mg/cap	102.50%	Between 90.0% To 110.0%
6.0	Microbial Test		
6.1	Total aerobic viable count	40 cfu/g	NMT 1000 cfu/g
6.2	Total Yeast and mould count	02 cfu/g	NMT 100 cfu/g
6.3	E.coli	Absent	Shall be absent/g
6.4	Salmonella	Absent	Shall be absent/10g
6.5	Staphylococcus aureus	Absent	Shall be absent/g
6.6	P. aeruginosa	Absent	Shall be absent/g

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Conclusion: Sample Complies As Per Ref. Specification No. FPS/BP/2217

Analysis By:

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Approved By:

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