

QUALITY CONTROL DEPARTMENT

[Certificate of Analysis]

(FORM 39, RULE 150 E (F) THE DRUG AND COSMETIC ACT, 1940 AND THE RULES THERE UNDER)

Product Name	: Iverheal Cream 1%	AR Number	: FP-10-2024/0942
Generic Name	: Ivermectin Cream 1.0% w/w	Sample Quantity	: 10 x 30gm.
Batch No.	: KEB113	Manufactured By	: Kureasia Pharma Pvt. Ltd.
Batch Size	: 300 kg	Manufactured For	: Healing Pharma India Pvt Ltd.
Date of Received	: 09/10/2024	Manufacturing Date	: 10/2024
Date of Analysis	: 09/10/2024	Expiry Date	: 09/2026
Mfg. Lic. No.	: 20/UA/2023 & 18/UA/SC/P-2023	Date of Completion	: 15/10/2024
Reference Protocol No	: KP/QC/FPS/049		

Sr. No	TEST PARAMETER	OBSERVATION	SPECIFICATIONS
1.	Description	A white soft mass filled in printed plastic lemi tube.	A white soft mass filled in printed plastic lemi tube.
2.	Identification (By High Performance Liquid Chromatography)	Meet the Requirement	In the Assay, The principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.
3.	Average fill weight	30.06 gm	The average net weight of the content of the 10 containers is not less than the labeled amount. 30 gm/tube.
4.	Uniformity of fill weight	-0.22% to +0.45%	The net weight of the contents of any single container is not less than 91 per cent and not more than 109 per cent. 30 gm $\pm$ 9.0%
5.	Assay : Ivermetin IP 1.0% w/w	0.99% w/w	Shelf Life Limit: Not less than 0.90 % and not more than 1.10 % (Not less than 90.00 % and not more than 110.00 % of Label Claim) Release Limit: (Not less than 95.00% and not more than 105.00% of Label Claim) Not less than 0.95% and not more than 1.05%
6.	Microbial contamination: Total aerobic microbial count Total Yeast and mould count Escherichia coli	10 cfu per g. Less than 10 cfu per g. Absent	Not more than 100 cfu per g. Not more than 10 cfu per g. Should be absent/g

Remark : Product complies/~~does not complies~~ as per IP/BP/USP/IH specification

Prepared by	Checked by	Approved by
Sign/Date	Sign/Date	Sign/Date