

Saintlife Pharmaceutical Ltd.

(An ISO -9001-2015/QMS Cert.Co.) GMP & WHO Certified Company.

323, Central hope –Town, industrial Area, Selaqui, Dehradun -248011 (U.K.)

Mobile No.:9967006091, E-mail:admin@johnleeindia.com

CERTIFICATE OF FINISHED PRODUCT OF ANALYSIS

(The Drugs & Cosmetics Act. 1940 & Rules there under)

Manuf.Lic.No.34/UA/2017

(Form -39)

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| | 33/ | UA | V/S | C/I | 2-2 | 01 | 7 |
|---|-----|----|-----|-----|-----|----|---|
| _ | | | _ | _ | _ | - | - |

| Name of Product | IVERJOHN-6 | A.R. No. | FP-088/03-2021 |
|-----------------|------------------------|-----------------|----------------|
| Generic Name | IVERMECTIN TABLETS USP | Sample Quantity | 60 Tablets |
| Batch No. | TA21046 | Batch Size | 3.0 Lacs |
| Date of Mfg. | 03/2021 | Date of Exp. | 02/2024 |
| Date of Receipt | 11/03/2021 | Date of Release | 13/03/2021 |
| | | | |

| S.No. | Test Parameter | Specification | Results |
|-------|-------------------------------|--|--|
| 1. | Description | White colour, round shape, biconvex, plain on both side and uncoated tablets.10X10 tablets packed in a carton. | White colour, round shape, biconvex, plain on both side and uncoated tablets.10X10 tablets packed in a carton. |
| 2. | Identification | Should be positive for ivermectin as per assay procedure. | Positive for ivermectin as per assay procedure. |
| 3. | Average weight | 225.0 mg ± 5.0 % | 225.97mg |
| 4. | Uniformity of weight | 225.0 mg ± 7.5 % | -3.78 % to +5.68% |
| 5. | Disintegration Time | Not more than 15 minutes | 3 minutes |
| 6. | Hardness | Not less than 2.0 Kg | 4.2 Kg |
| 7. | Thickness | 3.20 mm ± 0.20 mm | 3.39 mm |
| 8. | Diameter | 8.0 mm ± 0.20 mm | 8.02 mm |
| 9. | Friability | Not more than 1.0 % | 0.03 % |
| 10. | Not less than 80 % (Q) of the | | 89.46% to 101.55% |



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| 11. | Assay: Each uncoa | ated | | |
|-----|----------------------------------|------|--|-----------------|
| | tablet contains: Ivermectin USP | 6 mg | 5.40 mg to 6.60 mg (90.0% to 110.0%w/w of Label Claim | 5.97mg (99.50%) |

Opinion: The above material is complies / does not comply with the specification.

| | Analysed By | Approved By |
|-------------|-------------|-------------------------------|
| Sign/Date | 13/03/2021 | (4) Quality Con (2) [3]03 202 |
| Name | Poonam Rana | Department Sheetal Sharma |
| Designation | Analyst QC | Sr.Officer QC |