



MAXCURE NUTRAVEDICS LIMITED

Plot No.:13, Sector-6A, IIE., SIDCUL, Ranipur, Haridwar-249403, Uttrakhand, INDIA
Phone No.: +91-1334-239220, 239221, 239222. E-mail: works@maxcure.in
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

| | | | |
|-------------------------------------|---|-----------------------------------|---------------|
| Product Name : | ST. BOTANICA EC SALMON FISH OIL CAP LS 1X60 | | |
| Generic Name : | NA | | |
| Mfg. Lic. No. : | 10016012000340 | Market : | DOMESTIC |
| Batch No. : | HWAB01 | A. R. No. : | MF2018092506 |
| Mfg. Date : | 09/2018 | Pack Size : | 1X60 CAPSULES |
| Exp. Date / Best Before: | 08/2020 | Pack Type : | HDPE BOTTLE |
| Batch Size : | 150000 NOS | Sampled On : | 25/09/18 |
| Product Code : | 40032309 | Sample Quantity : | 120 CAPSULES |
| Specification No., Ver. No.: | STS/FP/40032309-00 | Sampled By : | Q.A. |
| Ref. STP No., Ver. No.: | STP/FP/40032309-00 | Analyzed By : | ANURAG |
| Manufactured For : | EMMBROS OVERSEAS LIFESTYLE PVT LTD | Date of Analysis : | 25/09/18 |
| Manufactured By : | Maxcure Nutravedics Limited (Plant-1) | Analysis Completion Date : | 30/09/18 |

| S.No. | TEST | ACCEPTANCE CRITERIA | RESULTS |
|-------|---|---|---|
| 1 | Description | Natural gelatin colored oblong shape enteric coated capsules containing pale yellow to red transparent viscous oily fluid packed in PET Bottle. | Natural gelatin colored oblong shape enteric coated capsules containing pale yellow to red transparent viscous oily fluid packed in PET Bottle. |
| 2 | Identification | Should be positive for EPA & DHA | positive for EPA & DHA |
| 3 | Average fill weight | 1000 mg \pm 7.5% | 1048.18mg |
| 4 | Average weight of Enteric coated soft gelatin capsule | 1507 mg \pm 7.5% | 1618.53 mg |
| 5 | Uniformity of fill Weight | Within \pm 7.5% of Average fill weight | -5.65% to +4.65% |
| 6 | Disintegration Time | Should not show any sign of disintegration in 0.1 N HCl for 2 hour after that should disintegrate within 1 hour in 6.8 phosphate buffer. | Not Break in 0.1N HCL For 2 hour AND 6.8 Phosphate buffer 22 Minitus & 44 Seconds. |
| 7 | Microbial Limit | ----- | ----- |
| (i) | Total bacterial count | Not more than 1000 cfu/gm | 70 cfu/gm |
| (ii) | Total Yeast & Mould Count | Not more than 100 cfu/gm | <10 cfu/gm |

Prepared By *[Signature]*
Officer/Executive-QC
(Sign & Date)

Checked By *[Signature]*
Operating Manager QC
(Sign & Date)

Approved By *[Signature]*
Head QC
(Sign & Date) 30/09/18

FORMAT No. : QAG-135/F01-00

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| Manufactured For : | EMMBROS OVERSEAS LIFESTYLE PVT LTD | Date of Analysis : | 25/09/18 |
| Manufactured By : | Maxcure Nutravedics Limited (Plant-I) | Analysis Completion Date : | 30/09/18 |

| S.No. | TEST | ACCEPTANCE CRITERIA | RESULTS |
|-------|--------------|------------------------|---------|
| (iii) | E.coli | Should be Absent/gm | Absent |
| (iv) | Salmonella | Should be Absent/10 gm | Absent |
| (v) | P.aeruginosa | Should be Absent/gm | Absent |
| (vi) | S.aureus | Should be Absent/gm | Absent |

CONCLUSION : The Finished Product complies as per IH Specification.

Prepared By *[Signature]*
Officer/Executive-QC
(Sign & Date) *30/09/18*

Checked By
Operating Manager QC
(Sign & Date) *[Signature]*
30/09/18

Approved By *[Signature]*
Head QC
(Sign & Date) *30/09/18*