

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 FISH OIL1000 CAP LS 1X60		
Generic Name :	Omega 3 Fatty Acids Soft Gelatin Capsule		
Mfg. Lic. No.:	10016012000340	Market:	Domestic
Batch No.:	HWAA01	A. R. No. :	MF2018072706
Mfg. Date:	07/2018	Pack Size :	1X60 CAPSULE
Exp. Date / Best Before:	06/2020	Pack Type:	PET BOTTLE
Batch Size:	200000 NOS	Sampled On:	27/07/18
Product Code:	40032083	Sample Quantity	: 120 CAPSULES
Specification No., Ver. No.:	STS/FP/40032083-00	Sampled By:	QA
Ref. STP No., Ver. No.:	STP/FP/40032083-00	Analyzed By:	MUKESH
Manufactured For:	EMMBROS OVERSEAS LIFESTYLE PVT LTD	Date of Analysis :	27/07/18
Manufactured By:	Maxcure Nutravedics Limited (Plant-I)	Analysis Complet	ion Date : 01/08/18

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 Hill Officer/Executive-QC (Sign & Date)

FORMAT No.: QAG-135/F01-00

Checked By
Operating Manager QC
(Sign & Date)

Approved By 01 08 18
Head QC
(Sign & Date)

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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 ± 7.5%	991.61mg
4	Average weight of Enteric coated soft gelatin capsule	1518 mg ± 7.5%	1495.47 mg
5	Uniformity of fill Weight	Within \pm 7.5% of Average fill weight	-2.15% to +1.65%
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.	In 2 Hour 0.1M HCL not break & 6.8Ph Phosphate Buffer Disintegration Time(24 minitus & 42 seconds)
7	Microbial Limit		
(i)	Total bacterial count	Not more than 1000 cfu/gm	50 cfu/gm
(ii)	Total Yeast & Mould Count	Not more than 100 cfu/gm	<10 cfu/gm

Prepared By Officer/Executive-QC (Sign & Date)

Checked By
Operating Manager Q
(Sign & Date)

Approved By
Head QC
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