

## 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** 

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name :	MUSC. XPECF.O. 100MGOM	3(18:12) SGCA PLS	1X60	
Generic Name :	Omega 3 Fatty Acids Soft Gelat	in Capsule	7	
Mfg. Lic. No.:	10016012000340	Market:	Domestic	
Batch No.:	HWAC02	A. R. No. :	MF2019050306	
Mfg. Date :	04/2019	Pack Size :	1X60 CAPSULES	
Exp. Date / Best Before:	03/2021	Pack Type :	HDPE BOTTLE	
Batch Size :	99960 NOS	Sampled On:	03/05/19	
Product Code:	40033174	Sample Quantity	:120 CAPSULE	
Specification No., Ver. No.:	STS/FP/40033174-00	Sampled By:	QA	
Ref. STP No., Ver. No.:	STP/FP/40033174-00	Analyzed By:	VINAY	
Manufactured For:	EMMBROS OVERSEAS LIFESTYLE PVT	Date of Analysis :	03/05/19	
Manufactured By:	Maxcure Nutravedics Limited (Plant-I)	Analysis Complet	ion Date : 08/05/19	

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%	994.5mg
4	Average weight of Enteric coated soft gelatin capsule	1458 mg ± 7.5%	1483.12 mg
5	Uniformity of fill Weight	Within ± 7.5% of Average fill weight	-2.65% to +2.77%
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 show any sign of disintegration in 0.1 N HCl for 2 hour after that disintegrate in 29 minutes 22 seconds in 6.8 phosphate buffer.
7	Microbial Limit		
(i)	Total bacterial count	Not more than 1000 cfu/gm	90 cfu/gm
(ii)	Total Yeast & Mould Count	Not more than 100 cfu/gm	<10 cfu/gm

Prepared By Haye Officer/Executive-QC

(Sign & Date)

Checked By Operating Manager QC (Sign & Date)

Approved By
Head QC 08 05 /19
(Sign & Date)

FORMAT No.: QAG-135/F01-01

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## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name :	MUSC. XPECF.O. 100MGOM.	3(18:12) SGCA PLS	1X60	
Generic Name :	Omega 3 Fatty Acids Soft Gelat	in Capsule		
Mfg. Lic. No.:	10016012000340	Market:	Domestic	
Batch No.:	HWAC02	A. R. No. :	MF201905	0306
Mfg. Date :	04/2019	Pack Size :	1X60 CAP	SULES
Exp. Date / Best Before:	03/2021	Pack Type:	HDPE BO	TTLE
Batch Size :	99960 NOS	Sampled On:	03/05/19	
Product Code :	40033174	Sample Quantity	: 120 CAPSU	JLE
Specification No., Ver. No.:	STS/FP/40033174-00	Sampled By:	QA	
Ref. STP No., Ver. No.:	STP/FP/40033174-00	Analyzed By:	VINAY	
Manufactured For:	EMMBROS OVERSEAS LIFESTYLE PVT	Date of Analysis :	03/05/19	
Manufactured By:	Maxcure Nutravedics Limited (Plant-I)	Analysis Complet	ion Date :	08/05/19

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

**CONCLUSION:** The Finished Product complies as per IH Specification.

Hay 8105/19

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

FORMAT No.: QAG-135/F01-01

Checked By Oblos

perating Manager ( (Sign & Date) Approved By Head QC (Sign & Date)

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