

Certificate of analysis

Softgel Seamega 4030 TG-XO Ultra - 500mg

Code : CAA-EP4030TGNXO500

Specifications

Batch number : QB142865-1
Format : 10 oval
Production date : 10/12/2020

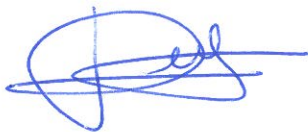
Microbiological

Test	Unit	Specification	Result	Method
Total plate count at 30 °C	/g	Max. 10000	<10	NF EN ISO 4833-1
E-Coli	/g	Absence	Not detected	NF EN ISO 16649-3
Salmonella	/25g	Absence	Not detected	IRIS BKR 23/07-10/11
Coliforms at 30°C	/g	Max. 100	<10	NF V08-050
Coagulase positive staphylococci	/g	Absence	Not detected	NF EN ISO 6888-3
Yeasts and Moulds	/g	Max. 100	<10	NF V08-059

This edition approved on the: January 26, 2021

Prepared by: Charlotte Crampon

Approved by: Guy Nguema Allogho



CERTIFICATE of COMPLIANCE of BULK PRODUCT

Capsugel hereby certify that:
 All documentation for the lot specified have been reviewed to confirm this lot was manufactured, packaged and tested (if applicable) at CAPSUGEL PLOERMEL and found to be in compliance with the current Dietary supplement Good Manufacturing Practices.

PRODUCT DESCRIPTION		SOFT GEL CAPSULES	NUTRITIONAL	
Product Name:	Softgel Seamega 4030 TG-XOUltra 500mg	Order Number:	3126335-1-1	
Product Code:	JC19238010	Customer Ref.:	CAA-EP4030TGN.XO500	
Lot Number:	QB142865/1	Customer Lot:	N.C.	
Capsule Size:	10 OVAL	Customer:	SAS SEANOVA - Soft	

Manufacturing Date: 10-Dec-2020

Total Weighed Quantity:	381.000 KG	Inventory quantity:	758 253 EA
Total Prepared Quantity:	380.500 KG	Accepted Capsules Quantity:	758 523 EA
Preparation Yield:	99.87%	Final Production Yield:	99.52%
<small>(Content Weight After Preparation / Actual Weight of Raw Material)</small>		<small>(Accepted Capsules Quantity / Theoretical Batch Size)</small>	

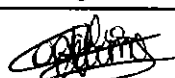
CAPSULE CONTENT FORMULA

Raw Material Name	Code	Quantity	Lot	Supplier Lot
Seamega oil 4030 TG-XO Ultra(seanova)	IG19214040	500.00 mg	QA140303	20370

CAPSULE SHELL FORMULA

Raw Material Name	Code	Lot
Gelatin 200 Bloom Fish (L)	IA04191051	QA140150
Gelatin 200 Bloom Fish (W)	IA04191052	QA139320
Glycerin 98%, pharma grade (EP/USP)	IF96177019	QA140204
Softened water	IF96192010	QA126011

This batch is released for further processing.

	Date	Job Title	First name Last name	Signature
Approved by:	11-Jan-2021	Qualified Person	Coralie Monteiro	

STANDARD FORM	GxP	Capsugel® A Lonza Company
BAPV – SOFTGEL SEAMEGA 4030 TG-XO ULTRA 500MG – JC19238010 Certificate of analysis – Bulk Product		

CAPSUGEL LOT NUMBER	CUSTOMER LOT NUMBER LOT CLIENT		
TESTS	SPECIFICATIONS	UNITS	RESULTS
<u>Appearance</u>			<i>NA</i>
Capsule – Size and Shape	10 Oval		<i>Complies</i>
Capsule – Shell Colour	Natural		<i>Complies</i>
<u>Masse</u>			
Content Average mass	463 to 538	mg	<i>499</i>
Average mass of full soft capsules	for information	mg	<i>675</i>
EDITOR (REDACTEUR)	Initials	<i>YHO</i>	
	Date	<i>30. Dec 2020</i>	
CHECKED BY (VERIFICATEUR)	Initials	<i>Lnab</i>	
	Date	<i>30. dec. 2020</i>	
<input checked="" type="checkbox"/> PASSED CONFORME	QUALITY CONTROL HEAD RESPONSABLE CQ	Initials	<i>MB</i>
<input type="checkbox"/> FAILED NON CONFORME		Date	<i>04 JAN. 2021</i>
Associated instruction (Instruction associée) : WI-000635			

11 JAN 2021 CXCW

Capsugel

A Lanza Company

RAPPORT DE PESEE

95 : FGCAPS

FORMULAIRE N° FOR-PRE-15004 Rev 03
Date d'impression : 10/12/2020 14:48

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DATE DE DEBUT : 10/12/2020 14:16

DATE DE FIN : 10/12/2020 14:16

STATUS: Complete

PRODUIT: Softgel Seamega 4030 TG-XOUltra 500mg

CODE: JC19238010

LOT: QB142865/1

Consommation unitaire



Fin des consommations



QUANTITE TOTALE A PESER (kg)	QUANTITE TOTALE PESEE (kg)
381.10000	381.00000

ORDRE DE FABRICATION: QB142865-1



TAILLE DU LOT : 762200 EA

SI683642

Ligne formule	Total à peser par matière (kg)	Total pesé par matière (kg)	Code matière première	Désignation matière première	N° lot matière première	Quantité par lot de MP (kg)	Balence	Pesée effectué par	Poids brut pesé (kg)	Tare (kg)	Poids net pesé (kg)	N° lot matière pesée
1	381.10000	381.00000	IG19214040	Seamega oil 4030 TG-XO Ultra(seanova)	QA140303-001 QA140303-002	190.50000 190.50000	BA0069	LEMAUM	480.50000	99.50000	381.00000	QB142865/1-W001

Production Cuve



Edité par

LEMAUM

10-Dec-2020

Certificate of analysis

SEAMEGA Oil 4030 TG-XO[®] ULTRA

Code: HUA-EP4030TGN.XO

Specification

Batch N° : 20370
 Production date : 03/11/2020
 Expiration date : 02/11/2023

Test

Test	Min. value	Max. value	Unit	Result	Method
APPEARANCE AT ROOM TEMPERATURE characteristics, bland, mild fish like			Clear oil	CO	Organoleptic
Acid value		1.0	mg KOH/g	0.2	SN002
Colour		6	Gardner	2	SN030
Peroxide value		3.0	meq O ₂ /kg	0.1	SN009
Anisidine value		8	-	3	SN014
Total oxidation		10	.	3	SN001
Absorbance 233 nm		0.60	AU	0.39	SN047
Triglycerides	90		A%	92	SN064
Oligomers		1.0	A%	ND	SN064
EPA; Eicosapentaenoic acid C20 :5			A%	46	SN003
DHA ; Docosahexaenoic acid C22 :6			A%	34	SN003
DPA; Docosapentaenoic acid C22 :5 n-3			A%	5	SN003
Total n-3 (7)			A%	92	SN003
Total n-3 : EPA, DHA, 18:3, 18:4, 20:4, 21:5, 22:5					SN003
EPA; Eicosapentaenoic acid C20 :5 (TG)	400	480	mg/g	430	SN003
DHA ; Docosahexaenoic acid C22 :6 (TG)	300	370	mg/g	327	SN003
DPA; Docosapentaenoic acid C22 :5 n-3 (TG)			mg/g	50	SN003
Total n-3 (7 TG)	800	960	mg/g	871	SN003
Total n-3 : EPA, DHA, 18 :3, 18 :4, 20 :4, 21 :5, 22 :5					SN003
EPA; Eicosapentaenoic acid C20 :5 (FA)	384	462	mg/g	413	SN003
DHA ; Docosahexaenoic acid C22 :6 (FA)	288	356	mg/g	314	SN003
Total n-3 (7 FA)	769	923	mg/g	837	SN003
Total n-3 : EPA, DHA, 18 :3, 18 :4, 20 :4, 21 :5, 22 :5					
Mixed tocopherol	3.0	4.5	mg/g	3.8	SN081

Test on Raw material EPAX (analysis transfer according to EPAX certificate)

ND: Not Detected
 CO: Compliant

Test	Min. value	Max. value	Unit	Result	Method
Frequency analyses from date : The following frequency analyses are analysed 1 times pr. Year with the latest results as reported below :				ddmmyy	60720
Unsaponifiable		3	%	CO	SN018
Frequency analyses from date : The following frequency analyses are analysed 3 times pr. Year with the latest results as reported below :				ddmmyy	90720
As, Arsenic		0.1	mg/kg	CO	SN500
Cd, Cadmium		0.005	mg/kg	CO	SN500
Pb, Lead		0.025	mg/kg	CO	SN500
Hg, Mercury		0.005	mg/kg	CO	SN500
DDT (sum : o,p' + p,p')		0.005	mg/kg	CO	SN500
DDD (sum : o,p' + p,p')		0.005	mg/kg	CO	SN021
DDE p,p'		0.005	mg/kg	CO	SN021
HCB		0.005	mg/kg	CO	SN021
PCBs all 209 Included IUPAC-no. 28, 52, 101, 138, 153,180		0.01	mg/kg	CO	SN521
Brominated flame retardants IUPAC no. 47, 99, 100, 153, 154,183		0.002	mg/kg	CO	SN500
DEHP		1	mg/kg	CO	SN021
Benzo(a)pyrene		1.0	ng/g	CO	SN501
Sum 4 PAH		5.0	ng/g	CO	SN501
Dioxinlike PCBs (TE WHO)		2	pg/g	CO	SN516
Dioxins+furans (TE WHO)		1	pg/g	CO	SN516
Dioxins+furans+dioxinlike PCBs (TE WHO)		2.5	pg/g	CO	SN516
Trans fatty acids (sum of 10)		0.9	%	CO	SN003

Test on Raw material EPAX (analysis transfer according to EPAX certificate)

CO: Compliant

This edition approved on the: November 05, 2020

Prepared by: Charlotte Crampon

Approved by: Guy Nguema Allogho