

Certificate of analysis

SEAMEGA Oil 4030 TG-XO® ULTRA

Code: HUA-EP4030TGN.XO

Specification

Batch N° : 21152
 Production date : 17/03/2021
 Expiration date : 16/03/2024

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	-	2	SN014
Total oxidation		10	.	2	SN026
Absorbance 233 nm		0.60	AU	0.41	SN047
Triglycerides	90		A%	93	SN064
Oligomers		1.0	A%	ND	SN064
EPA; Eicosapentaenoic acid C20 :5			A%	45	SN003
DHA ; Docosahexaenoic acid C22 :6			A%	34	SN003
DPA; Docosapentaenoic acid C22 :5 n-3			A%	5	SN003
Total n-3 (7)			A%	91	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	423	SN003
DHA ; Docosahexaenoic acid C22 :6 (TG)	300	370	mg/g	318	SN003
DPA; Docosapentaenoic acid C22 :5 n-3 (TG)			mg/g	50	SN003
Total n-3 (7 TG)	800	960	mg/g	851	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	406	SN003
DHA ; Docosahexaenoic acid C22 :6 (FA)	288	356	mg/g	305	SN003
Total n-3 (7 FA)	769	923	mg/g	818	SN003
Total n-3 : EPA, DHA, 18 :3, 18 :4, 20 :4, 21 :5, 22 :5					
Mixed tocopherol	3.0	4.5	mg/g	3.7	SN081

Tests on Raw material EPAX (analysis transfer according to certificate of Epax)

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	111120
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: March 30, 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:	3126887-3-1	
Product Code:	JC19238010	Customer Ref.:	CAA-EP4030TGNXO500	
Lot Number:	QB143370/1	Customer Lot:	N.C.	
Capsule Size:	10 OVAL	Customer:	SAS SEANOVA - Soft	

Manufacturing Date: 27-Apr-2021

Total Weighed Quantity:	440.500 KG	Inventory quantity:	858 636 EA
Total Prepared Quantity:	440.000 KG	Accepted Capsules Quantity:	858 886 EA
Preparation Yield:	99.89%	Final Production Yield:	96.94%
<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	QA141138	21152

CAPSULE SHELL FORMULA

Raw Material Name	Code	Lot
Gelatin 200 Bloom Fish (L)	IA04191051	QA140402
Gelatin 200 Bloom Fish (W)	IA04191052	QA140365
Glycerin 98%, pharma grade (EP/USP)	IF96177019	QA140817
Softened water	IF96192010	QA126011

This batch is released for further processing.

	Date	Job Title	First name Last name	Signature
Approved by:	20-Apr-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		QC

CAPSUGEL LOT NUMBER	CUSTOMER LOT NUMBER LOT CLIENT		
TESTS	SPECIFICATIONS	UNITS	RESULTS
<u>Appearance</u>			
Capsule – Size and Shape	10 Oval		Complies
Capsule – Shell Colour	Natural		Complies
<u>Masse</u>			
Content Average mass	463 to 538	mg	503
Average mass of full soft capsules	for information	mg	671
EDITOR (REDACTEUR)	Initials	YTD	
	Date	05. MAI. 2021	
CHECKED BY (VERIFICATEUR)	Initials	LNB	
	Date	05. MAI. 2021	
<input checked="" type="checkbox"/> PASSED CONFORME	QUALITY CONTROL HEAD RESPONSABLE CQ	Initials	MS
<input type="checkbox"/> FAILED NON CONFORME		Date	07 MAI 2021
Associated instruction (Instruction associée) : WI-000635			

20 MAI 2021 CION

Capsugel

A Lanza Company

RAPPORT DE PESEE

95 : FGCAPS

FORMULAIRE N° FOR-PRE-15004 Rev 03

Date d'impression : 27/04/2021 06:53

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DATE DE DEBUT : 26/04/2021 20:28

DATE DE FIN : 27/04/2021 06:45

STATUS: Complete

PRODUIT: Softgel Seamega 4030 TG-XOUltra 500mg

CODE: JC19238010

LOT: QB143370/1

Consommation unitaire



Fin des consommations



QUANTITE TOTALE A PESER (kg)	QUANTITE TOTALE PESEE (kg)
443.00000	440.50000

ORDRE DE FABRICATION: QB143370-1



SI699783

TAILLE DU LOT : 886000 EA

Ligne formule	Total à peser par matière (KG)	Total pesé par matière (KG)	Code matière première	Désignation matière première	N° lot matière première	Quantité per lot de MP (kg)	Balance	Pesée effectué par	Poids brut pesé (kg)	Tare (kg)	Poids net pesé (KG)	N° lot matière pesée
1	443.00000	440.50000	IG19214040	Seamega oil 4030 TG-XO Ultra(seanova)	QA141138-002	61.00000	BA0069	LEFRAY	337.00000	85.00000	252.00000	QB143370/1-W001
					QA141138-003	191.00000						
					QA141138-004	188.50000	BA0069	JMIGNONNE	525.00000	336.50000	188.50000	QB143370/1-W002

Production Cuve



Edité par

JMIGNONNEA

27-Apr-2021