

## CERTIFICATE OF ANALYSIS

Product: PronovaPure 360:240 EE EU		Batch no: 0015901459
Manufacturing date: 30.09.16	Retest date: 30.09.19	Specification and Revision no: 50355408-11 Rev. 4

Test	Specification	Result	Unit	Method
<b>Description</b>				
Appearance	Light yellow liquid	Light yellow liquid		PhEur 2063
Appearance	Slight fish-like odour	Slight fish-like odour		PhEur 2063
<b>Identity</b>				
EPA Identity	Positive	Positive		PhEur 2063/2.4.29 <sup>1</sup>
<i>Eicosapentaenoic acid ethyl ester</i>				
DHA Identity	Positive	Positive		PhEur 2063/2.4.29 <sup>1</sup>
<i>Docosahexaenoic acid ethyl ester</i>				
<b>Assay</b>				
C20:5 n-3, EPA EE		41,2	area %	PhEur 2063/2.4.29 <sup>1</sup>
<i>Eicosapentaenoic acid ethyl ester</i>				
C22:6 n-3, DHA EE		26,7	area %	PhEur 2063/2.4.29 <sup>1</sup>
<i>Docosahexaenoic acid ethyl ester</i>				
Total omega-3 acid EEs		81,4	area %	PhEur 2063/2.4.29 <sup>1</sup>
<i>EPA, DHA, C18:3 n-3, C18:4 n-3, C20:4 n-3, C21:5 n-3, C22:5 n-3</i>				
C20:5 n-3, EPA EE	Min 360	394	mg/g	PhEur 2063/2.4.29 <sup>1</sup>
<i>Eicosapentaenoic acid ethyl ester</i>				
C22:6 n-3, DHA EE	Min 240	251	mg/g	PhEur 2063/2.4.29 <sup>1</sup>
<i>Docosahexaenoic acid ethyl ester</i>				
EPA and DHA EEs	Min 600 - Max 700	644	mg/g	PhEur 2063/2.4.29 <sup>1</sup>
Total omega-3 acid EEs	Min 650	772	mg/g	PhEur 2063/2.4.29 <sup>1</sup>
<i>EPA, DHA, C18:3 n-3, C18:4 n-3, C20:4 n-3, C21:5 n-3, C22:5 n-3</i>				
C20:5 n-3, EPA FA	Min 329	360	mg/g	PhEur 2063/2.4.29 <sup>1</sup>
<i>Eicosapentaenoic acid as free fatty acid</i>				
C22:6 n-3, DHA FA	Min 221	231	mg/g	PhEur 2063/2.4.29 <sup>1</sup>
<i>Docosahexaenoic acid as free fatty acid</i>				
<b>Antioxidant</b>				
Mixed tocopherols	Min 1	1	mg/g	611081 (In-house)
<b>Organic impurities</b>				
Acid value	Max 0,5	<0,05	mg KOH/g	PhEur 2063/2.5.1
Peroxide value	Max 2,0	<0,1	meq/kg	PhEur 2063/2.5.5
Anisidine value	Max 10,0	2,3		PhEur 2063/2.5.36
Total oxidation (Totox)	Max 12	2		611136 (In-house)
Absorbance at 233 nm	Max 0,50	0,28	AU	PhEur 2063/2.2.25
Oligomers and partial glycerides	Max 3	0	area %	PhEur 2063/2.2.30
Cholesterol		0,5	mg/g	PhEur 2.4.32
<b>Periodic analyses</b>				
Periodic analyses tested		060116	ddmmyy	
<i>The following parameters are tested minimum once a year</i>				
Batchnumber, periodic analyses performed		B:0014680951		

## CERTIFICATE OF ANALYSIS

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Test	Specification	Result	Unit	Method
<b>Inorganic impurities</b>				
Hg, Mercury	Max 0,02	<0,005	mg/kg	USP <233>
Pb, Lead	Max 0,02	<0,008	mg/kg	USP <233>
Cd, Cadmium	Max 0,01	<0,002	mg/kg	USP <233>
As, Arsenic	Max 0,1	<0,008	mg/kg	USP <233>
<b>Organic impurities</b>				
Dioxins (TE WHO) <i>Sum PCDDs/PCDFs</i>	Max 1	0,36	pg/g	US EPA 1613
Dioxins and dioxin-like PCBs (TE WHO) <i>Sum PCDDs/PCDFs, non-ortho and mono-ortho PCBs</i>	Max 3	0,83	pg/g	US EPA 1613/1668
PCBs <i>IUPAC no: 28, 52, 101, 118, 138, 153, 180</i>	Max 0,015	0,00222	mg/kg	US EPA 1668
PCBs <i>Sum 209 congeners</i>	Max 0,03	0,00407	mg/kg	US EPA 1668
Benzo(a)pyrene	Max 1	1	ng/g	611536 (In-house)
PAHs <i>benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene</i>	Max 5	3	ng/g	611536 (In-house)

**Comment:**

PronovaPure 360:240 EE EU complies with the European Pharmacopoeia Monograph Omega-3 Acid Ethyl Esters 60 (2063), GOED Voluntary Monograph and EU regulation 1881/2006, as amended for metals, dioxins and PCBs, and polycyclic aromatic hydrocarbons (PAHs).

<sup>1</sup> The calculation of EPA and DHA as free fatty acids is part of the in-house method 611128.

Analysis controlled and approved by:

Sidsel Krogvig - Laboratory Technician

Date: 28.10.2016 09:44:53

COFA approved by:

Line Rebecca Gjelsås Storhaug - Qualified Person

Date: 28.10.2016 10:16:46