Norwegian Medicines Agency

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CERTIFICATE NUMBER: ***22/11225-14***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Norway confirms the following:
The manufacturer: ***Epax Norway AS***
Site address: ***Aarsaethervegen 17, Aalesund, 6006, Norway***
OMS Organisation Id. / OMS Location Id.: ***ORG-100019906 / LOC-100028636***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***9698*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Act of 4 December 1992 on Medicinal Products etc.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/ECtransposed in the following national legislation:
Act of 4 December 1992 on Medicinal Products etc.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-06-08***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [3]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Norwegian Medicines Agency (NoMA)
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Office adress: Grensesvingen 26, 0663 Oslo, Norway
post@noma.no

Letters should be adressed to the Norwegian Medicines Agency.
Please state our reference.
Tlf.: +47 22 89 77 00
IBAN.: NO 71 7694 05 00903

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Manufacture of active substance. Names of substances subject to inspection:
OMEGA-3-FATTY ACIDS AND THEIR DERIVATES FROM FISH OIL(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance:OMEGA-3-FATTY ACIDS AND THEIR DERIVATES FROM FISH OIL	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.5 Modification of extracted substance 3.2.6 Purification of extracted substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Ethyl-esterification, distillation, cold filtration, bleaching, mixing. 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

Section 1.2.2 applies to Omega-3-fatty acids and their derivates only.

Norwegian
Medicines Agency

2022-10-13

Name and signature of the authorised person of the Competent Authority of

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