To Whom It May Concern:

GMP certificate for Lýsi hf:

As a manufacturer of API (Active Pharmaceutical Ingredient) products Lýsi hf is a holder of a valid GMP certificate issued by the Icelandic Medicines Agency. The GMP cerificate verifies compliance with the pharmaceutical standard: EU GMP part II, Basic Requirements for Active Substances used as Satring Material. The signed cerificate can be found below but corresponding cerificate is available in the Eudra GMDP database: http://eudragmdp.ema.europa.eu

The Icelandic Medicines Agency issues a GMP certificate for the manufacture of API only and not for food supplements. The GMP certificate is thus only valid for active substances used as starting material for medicinal products. However, Lýsi hf applies GMP principle to manufacturing of all other products.

Reykjavík, 19 August 2019

Haraldur Sigurjónsson
Head of Quality Assurance
Lýsi hf

Icelandic Medicines Agency

CERTIFICATE NUMBER: ***IS/07/19***

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 Iceland confirms the following:
The manufacturer: ***Lýsi hf.***
Site address: ***Fiskislóð 5-9, Reykjavík, IS-101, Iceland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***047*** in accordance with Art. 40 of Directive 2001/83/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-05-16*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [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 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/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.*

17/7 2019

ICELANDIC MEDICINES AGENCY

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: API - various type of fish oil(en)
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.17 Other non-sterile medicinal products: fish oil in bulk drums(en)
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Manufacture of active substance. Names of substances subject to inspection :
FISH OIL(en)
FISH LIVER OIL(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : FISH OIL	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance Animal
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Deodorisation - Standardisation - Filtration 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance : FISH LIVER OIL	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance Animal
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Deodorisation - Standardisation - Filtration 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

	which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Any restrictions related to the scope of this certificate :

Section 1.2.2 applies to release of fish oil API

Clarifying remarks (for public users)

Section 1.2.2 applies to release of fish oil API

2019-07-17

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

Mr. Jon Petur Gudmundsson
Icelandic Medicines Agency
Tel:
Fax: