Lyfjastofnun
Icelandic Medicines Agency

Certificate No: IS/24/08

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

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

Has been inspected in accordance with the Medicinal Products Act, nr. 100/2020, as amended, and Regulation concerning the manufacture of medicinal products, No. 893/2004, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **28th of February 2024**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.

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 with the issuing authority.

24 May 2024

Andrea Þórhallsdóttir
Icelandic Medicines Agency

ICELANDIC MEDICINES AGENCY

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS
1.2 Non-sterile products
1.2.1 Non-sterile products (list of dosage forms) 1.2.1.6 Liquids for internal use
1.5 Packaging
1.5.1 Primary packing 1.5.1.1 Capsules, soft shell 1.5.1.6 Liquids for internal use 1.5.1.13 Tablets
1.5.2 Secondary packing
1.6 Quality control testing
1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate.

1.2: Relates to standardized blending of fish oil and olive oil, along with additional flavoring where applicable.

1.5: Products packed at the site are fish oil capsules, liquid fish oil and tablets that are not classified as medicinal products in Iceland.

24 May 2024

Andrea Þórhallsdóttir
Icelandic Medicines Agency

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