LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER: ***6.2.1-2017-019083***

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
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Sweden confirms the following:
The manufacturer: ***Lifecore Biomedical Inc.***
Site address: ***3515 Lyman Boulevard, Chaska, Minnesota, 55318, United States***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC and Art. 80(4) of Directive 2001/82/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 80(1) of Directive 2001/82/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-05-11*** , 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 and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]
- The principles of GMP for active substances [3] referred to in Article 51 of Directive 2001/82/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.

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[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.*

Part 2

Human Medicinal Products Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

Manufacture of active substance. Names of substances subject to inspection :
SODIUM HYALURONATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance : SODIUM HYALURONATE	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.2 Cell Culture : Bacterial 3.3.3 Isolation / Purification
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying 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 3.6.2 Microbiological testing excluding sterility testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing

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Clarifying remarks (for public users)

Secondary packaging, storage and distribution activities at 1245 Lakeview Dr, Chaska, Minnesota, 55318, USA are included in this certificate. 3.4.1: Aseptical processing after sterile filtration.

2017-09-29

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

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Medical Products Agency
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The following statement obtained from the European Medicines Agency EudraGMDP database applies to Lifecore Biomedical's European GMP CERTIFICATE NUMBER 6.2.1-2017-019083:

Due to the restrictions caused by COVID-19, the period of validity GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2023, except where clarifying remarks in the document state otherwise. Manufacturers, and importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are conducted where and when possible. Competent authorities reserve the right to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP certificates, as appropriate.