Health and Youth Care Inspectorate – Pharmaceutical Affairs

CERTIFICATE NUMBER: ***NL/H 16/1009546APIV2***

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 Netherlands confirms the following:
The manufacturer: ***Bouwhuis Enthoven B.V.***
Site address: ***Aakstraat 14, RAALTE, 8102HH, Netherlands***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-05-31*** , it is considered that it complies with :

- 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.

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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

Manufacture of active substance. Names of substances subject to inspection :
LYSOZYME HYDROCHLORIDE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance : LYSOZYME HYDROCHLORIDE	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.2 Extraction of substance from animal source
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	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 3.6.2 Microbiological testing excluding sterility testing

Clarifying remarks (for public users)

Following a risk-based review of GMP compliance information conducted on 6 June 2019, the validity period of this certificate is extended to 31 May 2020.

2019-06-06

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

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