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PUBLIC HEALTH SUPERVISORY SERVICE
HEALTH CARE INSPECTORATE

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 The Netherlands confirms the following:

The manufacturer

Site address

The 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: The Medicines Act, article 100.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **15 October 2013**, it is considered that it complies with the principles of GMP for active substances 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 Restricted of 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 EudraGMP. If it does not appear, please contact the issuing authority.

Issue Date:
Signature:

Inspector, Health Care Inspectorate, The Netherlands
+ 31 70 304 1624

Part 2

2	MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES and		
3.1	**Manufacture of Active Substance by Chemical Synthesis**	**Yes**	**No**
	3.1.1 Manufacture of active substance intermediates	☒	☐
	3.1.2 Manufacture of crude active substance	☒	☐
	3.1.3 Salt formation / Purification steps : <free text>	☒	☐
	3.1.4 Other <free text>	☐	☒
3.2	**Extraction of Active Substance from Natural Sources**	**Yes**	**No**
	3.2.1 Extraction of substance from plant source	☐	☒
	3.2.2 Extraction of substance from animal source	☐	☒
	3.2.3 Extraction of substance from human source	☐	☒
	3.2.4 Extraction of substance from mineral source	☐	☒
	3.2.5 Modification of extracted substance <specify source 1,2,3,4>	☐	☒
	3.2.6 Purification of extracted substance <specify source 1,2,3,4>	☐	☒
	3.2.7 Other <free text>	☐	☒
3.3	**Manufacture of Active Substance using Biological Processes**	**Yes**	**No**
	3.3.1 Fermentation	☐	☒
	3.3.2 Cell Culture <specify cell type>	☐	☒
	3.3.3 Isolation / Purification	☐	☒
	3.3.4 Modification	☐	☒
	3.3.5 Other <free text>	☐	☒
3.4	**Manufacture of sterile active substance (sections 3.1, 3.2, 3.3 to be completed as applicale**	**Yes**	**No**
	3.4.1 Aseptically prepared	☐	☒
	3.4.2 Terminally sterilised	☐	☒
3.5	**General Finishing Steps**	**Yes**	**No**
	3.5.1 Physical processing steps <specify>	☐	☒
	3.5.2 Primary Packaging (enclosing / sealing with direct contact)	☒	☐
	3.5.3 Secundary Packaging (also includes any labelling for ID or traceability)	☒	☐
	3.5.4 Other <free text>	☐	☒
3.6	**Quality Control Testing**	**Yes**	**No**
	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	☐	☒

Issue Date:
Signature:

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

N.a.

Date:

Name and signature of the authorised person of the competent Authority of the Netherland:

Ministerie van Buitenlandse Zaken

Gezien voor legalisatie van de handtekening

van: .....

De minister idse Zaken voor deze,

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Den Haag,