Chief Pharmaceutical Inspector

IWSC.405.4.2018.IPIO.1
WTC/0046_01_02/285

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 80(5) of Directive 2001/82/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Instytut Biotechnologii Surowic i Szczepionek BIOMED Spółka Akcyjna / IBSS BIOMED S.A.
Al. Sosnowa 8, 30-224 Kraków, POLAND

site address

Instytut Biotechnologii Surowic i Szczepionek BIOMED Spółka Akcyjna / IBSS BIOMED S.A.
Al. Sosnowa 8, 30-224 Kraków, POLAND

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2017, item 2211) in connection with registration no **71/WTC0046/API/15**.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **29-31/08/2018**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC, Directive 91/412/EEC and 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 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 EudraGMP. If it does not appear, please contact the issuing authority.

Chief Pharmaceutical Inspector

Paweł Piotrowski

date: 2018 -11- 28

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Paweł Piotrowski
Chief Pharmaceutical Inspector

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Suspension of inactivated Bordetella pertussis strain
- Salmonella typhi bacteria (inactivated)
- Inactivated Streptococcus pyogenes bacteria
- Inactivated Streptococcus pneumoniae bacteria
- Inactivated Streptococcus salivarius bacteria
- Inactivated Klebsiella pneumoniae bacteria
- Inactivated Moraxella catarrhalis bacteria
- Inactivated Escherichia coli bacteria
- Inactivated Haemophilus influenza bacteria
- Inactivated Corynebacterium pseudodiphtheriticum bacteria
- Inactivated Staphylococcus epidermidis bacteria
- Inactivated Staphylococcus aureus bacteria

3.3	**Manufacture of Active Substance using Biological Processes**
	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**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.4 Other** (storage of active substance before further stages of production)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.3 Microbiological testing** (including sterility testing) **3.6.4 Biological Testing**

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

Chief Pharmaceutical Inspector

date: 2018 -11- 28

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Tetanus toxoid
- Diphtheria toxoid

3.3	**Manufacture of Active Substance using Biological Processes**
	3.3.1 Fermentation **3.3.2 Cell Culture** (bacterial) **3.3.3 Isolation / Purification** **3.3.4 Modification**
3.4	**Manufacture of sterile active substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (sterilizing filtration) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.4 Other** (storage of active substance before further stages of production)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.3 Microbiological testing** (including sterility testing) **3.6.4 Biological Testing**

Chief Pharmaceutical Inspector

date: 2018 -11- 28

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Pseudomonas aeruginosa antigen from immunotype 1
- Pseudomonas aeruginosa antigen from immunotype 2
- Pseudomonas aeruginosa antigen from immunotype 3
- Pseudomonas aeruginosa antigen from immunotype 4
- Pseudomonas aeruginosa antigen from immunotype 5
- Pseudomonas aeruginosa antigen from immunotype 6
- Pseudomonas aeruginosa antigen from immunotype 7
- Pseudomonas aeruginosa antigens from immunotypes 3, 7

3.3	**Manufacture of Active Substance using Biological Processes**
	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 (sterilizing filtration) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.4 Other** (storage of active substance before further stages of production)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.3 Microbiological testing** (including sterility testing) **3.6.4 Biological Testing**

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date: 2018 -11- 28

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