Chief Pharmaceutical Inspector

IWPS.405.10.2020.SM.2
WTC/0119_02_02/154

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

Wytwórnia Surowic i Szczepionek BIOMED Sp. z o.o.
ul. Chełmska 30/34, 00-725 Warszawa, POLAND

site address

Wytwórnia Surowic i Szczepionek BIOMED Sp. z o.o.
ul. Chełmska 30/34, 00-725 Warszawa, 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 2020, item 944, as amended) in connection with registration no **63/WTC0119/API/15**.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **14-18/09/2020,** 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.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

date: 09.12.2020

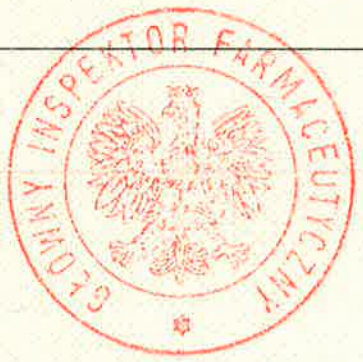
Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Paweł Piotrowski
Chief Pharmaceutical Inspector

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES
Active Substance(s): Viper Venom Antitoxin, concentrate

3.3	**Manufacture of Active Substance using Biological Processes**
	3.3.3 Isolation / Purification **3.3.5 Other:** Antisera of the animal source
3.4	**Manufacture of sterile active substance** (sections 3.1, 3.2, 3.3 to be completed as applicable)
	3.4.1 Aseptically prepared
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.3 Microbiological testing** (including sterility testing) **3.6.4 Biological Testing**



date: 09.12.2020

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Chief Pharmaceutical Inspector

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES
Active Substance(s):
Botulinum Antitoxin A, concentrate
Botulinum Antitoxin B, concentrate
Botulinum Antitoxin E, concentrate

3.3	**Manufacture of Active Substance using Biological Processes**
	3.3.2 Cell Culture (*Clostridium botulinum*) **3.3.3 Isolation / Purification** **3.3.5 Other:** Antisera of the animal source
3.4	**Manufacture of sterile active substance** (sections 3.1, 3.2, 3.3 to be completed as applicable)
	3.4.1 Aseptically prepared
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.3 Microbiological testing** (including sterility testing) **3.6.4 Biological Testing**

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

The certificate was issued on the basis of a remote inspection.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 09.12.2020

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