2024 -10- 0 1

CHIEF PHARMACEUTICAL INSPECTOR

ISF.405.123.2024.IP.1
WTC/0556_01_02/221

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Article 63(4) of Regulation (EU) No 536/2014

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Warszawski Uniwersytet Medyczny

ul. Żwirki i Wigury 61, 02-091 Warszawa, POLAND

site address

Warszawski Uniwersytet Medyczny

Laboratorium Badawcze – Bank Komórek Warszawskiego Uniwersytetu Medycznego

ul. Banacha 1b, 02-097 Warszawa, POLAND

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **241/0556/17** in accordance with Art. 61(1) of Regulation (EU) No 536/2014 Art. 38 and Art. 51a point 5 Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2024, item 686).

From the knowledge gained during inspection of this manufacturer the latest of which was conducted on **12/07/2024**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Commission Delegated Regulation (EU) 2017/1569.

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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/).

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.

Chief Pharmaceutical Inspector

Łukasz Pietrzak

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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared 1.1.1.4 Small volume liquids **1.1.3 Batch certification**
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.7 Tissue engineered products **1.3.2 Batch certification** 1.3.2.7 Tissue engineered products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility **1.6.4 Biological**

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

2024 -10- 01

Chief Pharmaceutical Inspector
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