

2021-06-22, r.



CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.54.2021.IP.1
WTC/0436_01_02/164

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Polski Bank Komórek Macierzystych S.A.
al. Jana Pawła II 29, 00-867 Warszawa, POLAND

site address

Polski Bank Komórek Macierzystych S.A.
ul. Działkowa 85, 02-234 Warszawa, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **239/0436/17** in accordance with Art. 13 of Directive 2001/20/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2020, item 944 as amended).

From the knowledge gained during inspection of this manufacturer the latest of which was conducted on **12-16/04/2021**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/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

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 1.1.1.5 Solids and implants 1.1.3 Batch certification
1.3	Biological medicinal products
	1.3.1 Biological medicinal products 1.3.1.3 Cell therapy products 1.3.1.7 Tissue engineered products 1.3.2 Batch certification 1.3.2.3 Cell therapy products 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 1.6.3 Chemical/Physical 1.6.4 Biological

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

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



Chief Pharmaceutical Inspector

Krajewska

Ewa Krajewska

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

