2022 -03- 17 r.

CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.38.2022.IP.1
WTC0348_01_01/59

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7, 05-400 Otwock, POLAND

site address

Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7, 05-400 Otwock, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **195/0348/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2021, item 1977 as amended)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **14–16/12/2021**, 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

Digitally signed by Bolea Petru
Date: 2023.07.11 09:53:16 EEST
Reason: MoldSign Signature
Location: Moldova

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.1 Aseptically prepared 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids **1.1.2 Terminally sterilised** 1.1.2.3 Small volume liquids 1.1.2.5 Other terminally sterilised prepared products: radionuclide generators **1.1.3 Batch certification**
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility **1.6.2 Microbiological: non sterility** **1.6.3 Chemical/Physical** **1.6.4 Biological**

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

Points 1.1.2.3, 1.1.2.5 concern manufacturing of radiopharmaceuticals.

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

Chief Pharmaceutical Inspector

Ewa Krajewska

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