CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.38.2023.IP.2
WTC/0348_01_01/66

Digitally signed by Bolea Petru
Date: 2023.07.11 09:53:38 EEST
Reason: MoldSign Signature
Location: Moldova

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

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. 13 of Directive 2001/20/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 **31/01-03/02/2023**, 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

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids **1.1.3 Batch certification**
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility **1.6.3 Chemical/Physical**

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

Point 1.1.1.4 concerns manufacturing of radiopharmaceuticals

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Chief Pharmaceutical Inspector

Krajewska

Ewa Krajewska

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

KANCELARIA NOTARIALNA
MONIKA SZULADZIŃSKA NOTARIUSZ
05-400 Otwock, ul. Karczewska 11 lok.1

Repertorium A- 2045 /20 23

Dnia dwudziestego czerwca

roku dwa tysiące dwudziestego trzeciego

POŚWIADCZAM zgodność powyższego odpisu z okazanym dokumentem .....

Pobrano: .....

-taksę notarialną z §12 rozporządzenia Ministra Sprawiedliwości z dnia 28.06.2004r. (Dz. U. Nr 148, poz. 1564, ze zm.)- 12 zł

-podatek VAT 23% z art. 146a ustawy z dnia 11.03.2004r. (Dz. U. Nr 54, poz. 535, ze zm.)- 2,76 zł

MONIKA SZULADZIŃSKA NOTARIUSZ W OTWOCKU 1

Monika Szuladzińska
M. Szuladzińska
Notariusz

MONIKA SZULADZIŃSKA NOTARIUSZ W OTWOCKU 1