CHIEF PHARMACEUTICAL INSPECTOR

2021 -06- 08

IWSF.405.48.2021.IP.2
WTC/0299_03_01/151

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 and importer

Centrala Farmaceutyczna „CEFARM" Spółka Akcyjna

ul. Jana Kazimierza 16, 01-248 Warszawa, POLAND

site address

Centrala Farmaceutyczna „CEFARM" Spółka Akcyjna

ul. I. Krasickiego 65, 97-500 Radomsko, POLAND

has been inspected under the national inspection programme in connection with importation authorisation No. **054/0299/15** 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 and importer, the latest of which was conducted on **12-15/04/2021** 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 and importation 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.

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	
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

Point 1.6.3 applies only to visual control of medicinal products.

2 IMPORTATION OF HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported investigational medicinal products**
	2.1.3 Chemical/Physical
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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

Point 2.1.3. applies only to visual control of medicinal products.

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

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

Chief Pharmaceutical Inspector

Ewa Krajewska

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