



Chief Pharmaceutical Inspector

IWZJ.405.87.2018.ER.1
WTC/0299_03_01/166

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

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

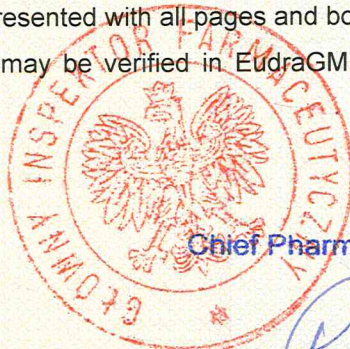
has been inspected under the national inspection programme in connection with manufacturing authorisation No. **054/0299/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2017, item 2211).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **24-25/04/2018**, 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.



Chief Pharmaceutical Inspector

date: 2018 -07- 10

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57


Paweł Piotrowski
Chief Pharmaceutical Inspector

Part 2

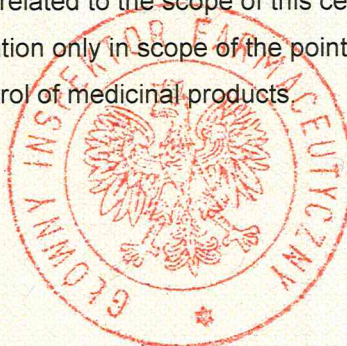
Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	Sterile Products
	1.1.3 Batch certification
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:

Points 1.1.3 and 1.2.2 Batch Certification only in scope of the point 1.5.2.

Point 1.6.3 applies only to visual control of medicinal products.



date: 2018 -07- 1 0

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