



*Chief Pharmaceutical Inspector*

**IWPS.405.13.2018.ER.1**  
**WTC/0108\_01\_01/297**

**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 and importer

**AFLOFARM FARMACJA POLSKA Sp. z o.o.**  
**ul. Partyzancka 133/151, 95-200 Pabianice, POLAND**

site address

**AFLOFARM FARMACJA POLSKA Sp. z o.o.**  
**ul. Krzywa 2, 95-030 Rzgów, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **051/0108/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6<sup>th</sup> of September 2001 (Journal of Laws from 2017, item 2211).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **11-14/09/2018**, 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 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.



*Chief Pharmaceutical Inspector*

**Paweł Piotrowski**

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**Chief Pharmaceutical Inspector**

date: **2018 -12- 0 5**

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

## Part 2

Human Medicinal Products

### 1 MANUFACTURING OPERATIONS

|            |   |
|------------|---|
| <b>1.2</b> | <b>Non-sterile products</b>   |
|            | <b>1.2.1 Non-sterile products</b><br>1.2.1.5 Liquids for external use<br>1.2.1.6 Liquids for internal use<br><br><b>1.2.2 Batch certification</b> |
| <b>1.4</b> | <b>Other products or processing activity</b>  |
|            | <b>1.4.1 Manufacture of:</b><br>1.4.1.1 Herbal products   |
| <b>1.5</b> | <b>Packaging</b>  |
|            | <b>1.5.1 Primary packing</b><br>1.5.1.5 Liquids for external use<br>1.5.1.6 Liquids for internal use<br><br><b>1.5.2 Secondary packing</b>        |
| <b>1.6</b> | <b>Quality control testing</b>  |
|            | <b>1.6.3 Chemical/Physical</b>  |

### 2 IMPORTATION OF MEDICINAL PRODUCTS

|            |   |
|------------|---|
| <b>2.1</b> | <b>Quality control testing of imported medicinal products</b> |
|            | <b>2.1.3 Chemical/Physical</b>                                |

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

Points: 1.2.1.5, 1.2.1.6, 1.5.1.5, 1.5.1.6 include also manufacturing of medicinal products containing highly potent substances.

date: **2018 -12- 05**

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