CERTIFICATE No. GIF-IW-400/0108_02_01/04/172/17

Chief Pharmaceutical Inspector

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. Szkolna 31, 95-054 Ksawerów, 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 6th of September 2001 (Journal of Laws from 2016, item 2142).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **09-11/05/2017**, 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.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -07- 27

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-400/0108_02_01/04/172/17

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: powders 1.2.1.12 Suppositories 1.2.1.13 Tablets 1.2.1.17 Other non-sterile medicinal product: raw materials used for preparing medicinal products in the pharmacy according to doctor's prescription or Pharmacopoeia formula **1.2.2 Batch certification**
1.4	**Other products or processing activity**
	1.4.1 Manufacture of: 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.8 Other solid dosage forms: powders 1.5.1.11 Semi-solids 1.5.1.12 Suppositories 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: raw materials used for preparing medicinal products in the pharmacy according to doctor's prescription or Pharmacopoeia formula **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.2 Microbiological: non sterility **1.6.3 Chemical/Physical**

date: 2017 -07- 27

Acting Chief Pharmaceutical Inspector
Zbigniew Niewójt

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-400/0108_02_01/04/172/17

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing: granules, bulk tablets

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

Points: 1.2.1.1, 1.2.1.8, 1.2.1.12, 1.2.1.13, 1.5.1.1, 1.5.1.5, 1.5.1.8, 1.5.1.11, 1.5.1.12, 1.5.1.13 include also manufacturing of medicinal products containing highly potent substances.

Points: 1.2.1.1, 1.2.1.13, 1.5.1.1, 1.5.1.13 include also manufacturing of medicinal products containing substances causing allegric or intolerance reactions.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2017 -07- 27

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector