CERTIFICATE No. GIF-IW-400/0053_01_01/04/35/17

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

ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.
ul. Annopol 6 B, 03-236 Warszawa, POLAND

site address

ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.
ul. Annopol 6 B, 03-236 Warszawa, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **087/0053/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2008, No. 45, item 271 with amendments).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **06-08/12/2016**, 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 INSPEKTORAT FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -01- 24

Chief Pharmaceutical Inspectorate
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Zbigniew Niewójt
Chief Pharmaceutical Inspector

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.13 Tablets **1.2.2 Batch certification**
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.2 Microbiological: non sterility **1.6.3 Chemical/Physical**

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

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

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