CHIEF PHARMACEUTICAL INSPECTOR

2021 -09- 2 1

IWSF.405.95.2021.IP.1
WTC/0196_02_01/245

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

Tarchomińskie Zakłady Farmaceutyczne „ Polfa" Spółka Akcyjna

ul. Fleminga 2, 03-176 Warszawa, POLAND

site address

Tarchomińskie Zakłady Farmaceutyczne „ Polfa" Spółka Akcyjna

ul. Fleminga 2, 03-176 Warszawa, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **078/0196/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2021, item 974 as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **21-25/06/2021**, 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 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 Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.8 Other solid dosage forms: granules for oral suspension, powders for oral suspension 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 1.5.1.5 Liquids for external use 1.5.1.8 Other solid dosage forms: granules for oral suspension, powders for oral suspension 1.5.1.13 Tablets **1.5.2 Secondary packing**

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

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

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

Chief Pharmaceutical Inspector

Ewa Krajewska

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