2024 -09- 17

ISF.405.112.2024.IP.2
WTC/0047_01_01/203

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

Farmaceutyczna Spółdzielnia Pracy „GALENA"

ul. Dożynkowa 10, 52-311 Wrocław, POLAND

site address

Farmaceutyczna Spółdzielnia Pracy „GALENA"

ul. Krucza 62, 53-411 Wrocław, POLAND

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **162/0047/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2024, item 686).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **28/06/2024**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572.

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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/).

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 EudraGMDP. If it does not appear, please contact the issuing authority.

Chief Pharmaceutical Inspector

Łukasz Pietrzak

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
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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
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.13 Tablets **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:
Part 1 except for distribution.

2024 -09- 17

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Chief Pharmaceutical Inspector

Łukasz Pietrzak

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