



ISF.405.87.2026.IP.2
WTC/0047_01_01/162

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER¹

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 2026, item 612 as amended).

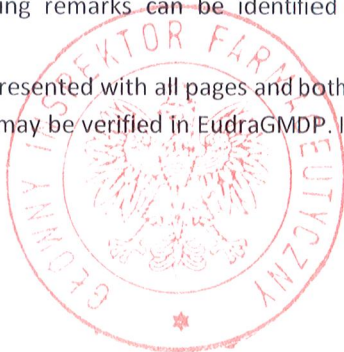
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **26/05/2026 – 29/05/2026**, it is considered that it complies with the Good Manufacturing Practice laid down in Directive (EU) 2017/1572.

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 EudraGMP website (<http://eudragmp.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 EudraGMP. If it does not appear, please contact the issuing authority.



Chief Pharmaceutical Inspector

Lukasz Pietrzak
Lukasz Pietrzak

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.

2023-07-23



Chief Pharmaceutical Inspector

Łukasz Pietrzak

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 94(1) of Regulation (EU) 2019/6 is also applicable to importers.