*Chief Pharmaceutical Inspector*

**IWPS.405.121.2019.KK.1**
**WTC/0101_01_01/285**

# 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

**Laboratorium Galenowe Olsztyn sp. z o.o.**
**Ul. Spółdzielcza 25A, 11-001 Dywity, POLAND**

site address

**Laboratorium Galenowe Olsztyn sp. z o.o.**
**Ul. Spółdzielcza 25A, 11-001 Dywity, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **055/0101/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2019, item 499).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **01-03/10/2019**, 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.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

**date:** 2019 -12- 20

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

**Paweł Piotrowski**
**Chief Pharmaceutical Inspector**

**Part 2**

| Human Medicinal Products |
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|---|---|
| **1 MANUFACTURING OPERATIONS** | |
| **1.1** | **Sterile Products** |
| | **1.1.3 Batch certification** |
| **1.2** | **Non-sterile products** |
| | **1.2.1 Non-sterile products**<br>1.2.1.5 Liquids for external use<br>1.2.1.6 Liquids for internal use<br>1.2.1.8 Other solid dosage forms: powders<br>1.2.1.11 Semi-solids<br>1.2.1.12 Suppositories<br>1.2.1.13 Tablets<br>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<br>**1.2.2 Batch certification** |
| **1.4** | **Other products or processing activity** |
| | **1.4.1 Manufacture of:**<br>1.4.1.1 Herbal products |
| **1.5** | **Packaging** |
| | **1.5.1 Primary packing**<br>1.5.1.5 Liquids for external use<br>1.5.1.6 Liquids for internal use<br>1.5.1.8 Other solid dosage forms<br>1.5.1.11 Semi-solids<br>1.5.1.12 Suppositories<br>1.5.1.13 Tablets<br>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<br>**1.5.2 Secondary packing** |

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|---|---|
| **1.6** | **Quality control testing** |
| | **1.6.2 Microbiological: non sterility**<br>**1.6.3 Chemical/Physical** |

Any restrictions or clarifying remarks related to the scope of this certificate:
**Point 1.1.3 only in scope of certification of the repackaged finished product.**

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

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