CHIEF PHARMACEUTICAL INSPECTOR

ISF.405.47.2026.IP.2
WTC/0108_03_02/83

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:

AFLOFARM FARMACJA POLSKA Sp. z o.o.
ul. Partyzancka 133/151, 95-200 Pabianice, POLAND

site address:

AFLOFARM FARMACJA POLSKA Sp. z o.o.
ul. Partyzancka 133/151, 95-200 Pabianice, POLAND

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2025, item 750 as amended) in connection with the entry in the Register no **84/WTC0108/API/15.**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **10/02/2026 – 13/02/2026,** it is considered that it complies with the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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.

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.

2026 -04- 11

Chief Pharmaceutical Inspector
Łukasz Pietrzak

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- **Marjoram herb extract**

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1 Extraction of substance from plant source
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (digest, strain)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

2026 -04- 11

Chief Pharmaceutical Inspector

Łukasz Pietrzak