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ISF.405.35.2024.IP.2
WTC/0108_01_02/61

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. Krzywa 2, 95-030 Rzgów, 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 2022, item 2301 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 **26/01/2024** it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572 and 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.

acting Chief Pharmaceutical Inspector

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**Active Substance(s):** Macerate from 5 g of the marshmallow root

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 (mixing, maceration)



acting Chief Pharmaceutical Inspector


Marcin Wójcik