



CHIEF PHARMACEUTICAL INSPECTOR

2024 -04- 2 2

ISF.405.35.2024.IP.3
WTC/0108_01_02/62**CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES
FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE**

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

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

The active substance importer

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**

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) and in connection with registration no **84/WTC0108/API/15**.

From the knowledge gained during inspection of this active substance importer, the latest of which was conducted on **26/01/2024** it is considered that it complies with the principles of good distribution practice for active substances referred to in article 47 of Directive 2001/83/EC.

This certificate reflects the status of the site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

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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