ISF.405.103.2025.IP.1
WTC/0647_01_01/221

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 94(1) of Regulation (EU) 2019/6

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/
confirms the following:

the manufacturer:

Sieć Badawcza Łukasiewicz - Instytut Przemysłu Organicznego
ul. Annopol 6, 03-236 Warszawa, POLAND

site address:

Sieć Badawcza Łukasiewicz - Instytut Przemysłu Organicznego
ul. Annopol 6, 03-236 Warszawa, POLAND

is an active substance manufacturer that has been inspected in accordance with Art. 123 (1) to (6) of Regulation (EU) 2019/6 and Art 51g 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 **179/WTC0647/API/23.**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **17/06/2025 – 18/06/2025,** it is considered that it complies with the principles of GMP for active substances referred to in Article 93(2) of Regulation 2019/6.

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.

2025 -09- 11

Chief Pharmaceutical Inspector
Łukasz Pietrzak

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Amitraz

3.1	**Wytwarzanie substancji czynnych drogą syntezy chemicznej**
	3.1.3. Salt formation / Purification steps (Leaching)
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, micronisation, sieving) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality control testing**
	3.6.1. Physical / Chemical testing

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

2025 -09- 11

Chief Pharmaceutical Inspector

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