



Główny Inspektor Farmaceutyczny

IWSC.405.22.2019.IPIO.1

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVESUBSTANCES 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 as amended

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

The active substance importer

**Przedsiębiorstwo Produkcyjno – Handlowe “EWA” S.A.,
ul. Zamkowy Folwark 9, 63-700 Krotoszyn, POLAND**

site address

**Przedsiębiorstwo Produkcyjno – Handlowe “EWA” S.A.,
ul. Zamkowy Folwark 9, 63-700 Krotoszyn, POLAND**

has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2019, item 499) in connection with registration no **21/WTC0030/API/15**.

From the knowledge gained during inspection of this active substance importer, the latest of which was conducted on **19-21/02/2019**, 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.

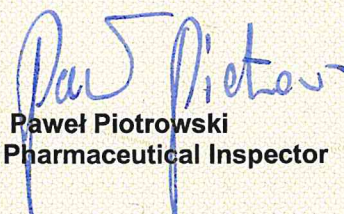
This certificate reflects the status of the site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management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

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.



date: **2019 -05- 17**

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Paweł Piotrowski
Chief Pharmaceutical Inspector

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

