



Chief Pharmaceutical Inspector

IWZJ.405.12.2018.ER.2

WTC/0098_01_06/19

**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(5) of Directive 2001/83/EC as amended

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the active substance importer and distributor

ICN Polfa Rzeszów S.A.

ul. Przemysłowa 2, 35-959 Rzeszów, POLAND

site address

ICN Polfa Rzeszów S.A.

ul. Przemysłowa 2, 35-959 Rzeszów, 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 2017, item 2211) in connection with registration no **98/WTC0098/API/15**.

From the knowledge gained during inspection of this active substance importer and distributor, the latest of which was conducted on **07-09/11/2017** 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.

date: 2018 -02- 0 6

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acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

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Chief Pharmaceutical Inspector