GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

2023 -05-04 , r.





CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.40.2023.IP.1 WTC/0510_01_01/75

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

IMCD POLSKA Sp. z o.o. ul. Domaniewska 32, 02-672 Warszawa, POLAND

site address

IMCD POLSKA Sp. z o.o. ul. Domaniewska 32, 02-672 Warszawa, 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 2022, item 2301) in connection with registration no **99/WTC0510/API/15**.

From the knowledge gained during inspection of this active substance importer and distributor, the latest of which was conducted on **08/02/2023** 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.

Chief Pharmaceutical Inspecto

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