2022 -01- 13

IWSF.405.1.2022.IP.1
WTC/0098_01_01_02/1

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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 manufacturer and importer

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 under the national inspection programme in connection with manufacturing authorisation No. **174/0098/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2021, item 1977 as amended).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **12-15/10/2021**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing and importation 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.

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 EudraGMP. If it does not appear, please contact the issuing authority.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: granules for oral solution 1.2.1.11 Semi-solids **1.2.2 Batch certification**
1.4	**Other products or processing activity**
	1.4.1 Manufacture of: 1.4.1.2 Homoeopathic products
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.2 Microbiological: non sterility **1.6.3 Chemical/Physical**

Any restrictions or clarifying remarks related to the scope of this certificate:

Points 1.2.1.11, 1.5.1.11 include medicinal product containing sensitizers.
Points 1.2.1.8, 1.4.1.2 include stage of samples retention.

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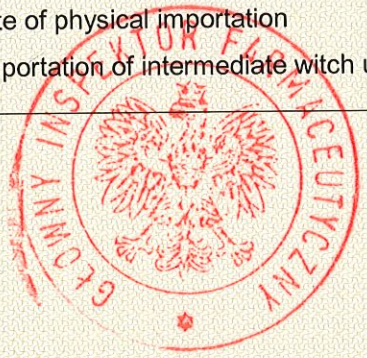
Importation of Human Medicinal Products

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile Products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
2.3	**Other importation activities**
	2.3.1 Site of physical importation 2.3.2. Importation of intermediate witch undergoes further processing: granules



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