2021 -04- 15

CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.20.2021.IP.1
WTC/0305_01_01/81

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Drwalewskie Zakłady Przemysłu Bioweterynaryjnego Spółka Akcyjna

ul. Grójecka 6, 05-651 Drwalew, POLAND

site address

Drwalewskie Zakłady Przemysłu Bioweterynaryjnego Spółka Akcyjna

ul. Grójecka 6, 05-651 Drwalew, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **119/0305/15** in accordance with Art. 44 of Directive 2001/82/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2020, item 944).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **08-10/02/2021**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 91/412/EEC.

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.

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.

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

www.gif.gov.pl
gif@gif.gov.pl

Part 2

Veterinary 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: single-dose powders and multidose powders 1.2.1.11 Semi-solids 1.2.1.13 Tablets 1.2.1.16 Veterinary premixes **1.2.2 Batch certification**
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: single-dose powders and multidose powders 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.1.16 Veterinary premixes **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.2 Microbiological: non sterility **1.6.3 Chemical/Physical** **1.6.4 Biological**

Any restrictions or clarifying remarks related to the scope of this certificate:
Points 1.2.1.16 and 1.5.1.16 also apply to products containing penicillin.

The certificate was issued on the basis of remote inspection.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Chief Pharmaceutical Inspector
Ewa Krajewska

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

www.gif.gov.pl
gif@gif.gov.pl