2023 -03- 2 0

CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.22.2023.IP.2
WTC/0167_01_02/37

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 94(1) of Regulation No 2019/6.

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

Nobilus Ent Tomasz Koźluk
ul. Swarzewska 45, 01-821 Warszawa, POLAND

site address

Nobilus Ent Tomasz Koźluk
ul. Zegrzyńska 22a, 05-110 Jabłonna, POLAND

Is an active substance manufacturer that 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) or Art. 123(6) of Regulation (EU) 2019/6 and Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301) in connection with the entry in the Register no **50/WTC0167/API/15**..

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **24–27/01/2023**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572 / Directive 91/412/EEC and the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

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

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES
Active Substance(s): - beta – Acetylodigoxin - Dextran cross-linked

4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES**
	Distribution

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES
Active Substance(s): - Digitoxin - Lanatoside C - Imatinib mesylate form alpha - Diethylamine salicylate - Clozapine

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES**
	Distribution

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