CHIEF PHARMACEUTICAL INSPECTOR

2024 -08- 01

ISF.405.89.2024.IP.2
WTC/0167_01_02/159

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

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 the following national legislation: Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2024, item 686) 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 **09/05/2024,** it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572 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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu /)

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

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Chief Pharmaceutical Inspector

Łukasz Pietrzak

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

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- **Metildigoxin, β–Methyldigoxin**
- **Aluminium chloride 25% sol.**
- **Deslanoside**
- **α-Escin**
- **Esculin**
- **Flutamide**
- **Aescin Sodium Salt**
- **Escin Sodium Polysulphate**

3.5	**General Finishing Steps**
	3.5.4 Other (distribution)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- **Digoxin**
- **β-Escin Amorphous**
- **β-Escin Crystalline**
- **Timonacic**
- **Mesna**

3.5	**General Finishing Steps**
	3.5.4 Other (distribution)

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