2023 -03- 2 0

CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.22.2023.IP.1
WTC/0167_02_02/36

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. Metalowa 6a, 99-300 Kutno, 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

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** • β – Acetyldigoxin

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance **3.1.3 Salt formation / Purification steps** (chromatography, crystallization)
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1 Extraction of substance from plant source **3.2.6 Purification of extracted substance from plant source**
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, milling) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** • **Digitoxin**

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance from plant source (purification steps of the substance, obtained from plant extract) **3.2.7 Other** (maceration of the suspension, filtration on the charcoal, crystallization)
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, miling) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** • Dextran Cross-Linked

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance **3.1.3 Purification steps** (washing)
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, sieving) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES
Active Substance(s): - Lanatoside C

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1 Extraction of substance from plant source **3.2.5 Modification of extracted substance from plant source** **3.2.6 Purification of extracted substance from plant source**
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, milling) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** - Imatinib mesylate form alpha

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance **3.1.3 Purification steps** (obtaining Imatinib Mesylate) **3.1.4 Other** (washing, aggregation)
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, grinding, granulation) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES
Active Substance(s): - Diethylamine salicylate

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance **3.1.3 Salt formation / Purification steps** (crystallization)
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** - Clozapine

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (milling) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES**
	Import

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

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Ewa Krajewska

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