Chief Pharmaceutical Inspector

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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

NYSK Holdings LLCOP
Boris Trajkovski str. No 73, 1000 Skopje, North Macedonia

site address

NYSK Holdings LLCOP
Boris Trajkovski str. No 73, 1000 Skopje, North Macedonia

has been inspected in connection with marketing authorization(s) listing manufacturer located outside of the European Economic Area in accordance with Art. 8(2), of Regulation 726/2004/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2019, item 499).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **09-13/12/2019**, 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 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 INSPEKTOR FARMACEUTYCZNY

date: 2020 -03- 06

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Paweł Piotrowski
Chief Pharmaceutical Inspector

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.17 Other non-sterile medicinal product: raw materials used for preparing medicinal products in the pharmacy according to doctor's prescription of Pharmacopoeia formula.
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.17 Other non-sterile medicinal products: raw materials used for preparing medicinal products in the pharmacy according to doctor's prescription of Pharmacopoeia formula. **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate:
Points 1.2.1.17 and 1.5.1.17 concern Cannabis extract.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2020 -03- 06

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