2021 -12- 0 6

IWSF.405.125.2021.IP.2
WTC/0594_01_01/334

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. 80(5) of Directive 2001/82/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

NYSK Holdings LLCOP

112 Str. no.217, Kjojlija, Municipality Petrovec, 1000 Skopje, NORTH MACEDONIA

site address

NYSK Holdings LLCOP

112 Str. no.217, Kjojlija, Municipality Petrovec, 1000 Skopje, NORTH MACEDONIA

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2021, item 974 as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **06–10/09/2021** it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC, 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.

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):** – Cannabis extract

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**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** – Marycan (Cannabis sativa flower, dried)

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (cutting, drying, trimming, final drying) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)

Any restrictions or clarifying remarks related to the scope of this certificate:

The certificate was issued on the basis of a remote inspection.

Chief Pharmaceutical Inspector

Ewa Krajewska

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fax 22 635 99 57
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2021 -12- 0 6

IWSF.405.125.2021.IP.1
WTC/0594_01_02/333

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC as amended

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

NYSK Holdings LLCOP

112 Str. no.217, Kjojlija, Municipality Petrovec, 1000 Skopje, NORTH MACEDONIA

site address

NYSK Holdings LLCOP

112 Str. no.217, Kjojlija, Municipality Petrovec, 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 2021, item 974 as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **06–10/09/2021,** 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.

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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**
	1.6.2 Microbiological: non sterility **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 standarised liquid extract of Cannabis and dried Cannabis flowers.

The certificate was issued on the basis of a remote inspection.

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