Agency For Medicinal Products And Medical Devices Of Croatia

CERTIFICATE NUMBER: ***530-10/23-06/03; 381-13-08/284-23-12***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

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

The competent authority of Croatia confirms the following:
The manufacturer: ***New Garden Pharma D.O.O.E.L. Skopje***
Site address: ***Kp 356/15 Ko Cojlija St. 110 No. 104, Cojlija, 1043, North Macedonia***
OMS Organisation Id. / OMS Location Id.: ***ORG-100049243*** / ***LOC-100083712***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-05-25***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [3]
- The principles of GMP for active substances [3] 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 EudraGMDP. If it does not appear, please contact the issuing authority.

[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Manufacture of active substance. Names of substances subject to inspection:
CANNABIS EXTRACT(en)
CANNABIS SATIVA DRIED FLOWERS(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance: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 Plant 3.2.6 Purification of extracted substance Plant
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) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance:CANNABIS SATIVA DRIED FLOWERS	
3.2	**Extraction of Active Substance from Natural Sources**

	3.2.1 Extraction of substance from plant source
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, trimming 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

1.2.1.6. Liquids for internal use refer to oral solutions and herbal products only. This certificate refers to Cannabis Sativa Dried Flowers and Cannabis Extract as active substances for medicinal use. Inspection and issuance of this GMP certificate were done without relationship to marketing authorisation.

2023-09-21

Name and signature of the authorised person of the Competent Authority of Croatia

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Confidential
Agency For Medicinal Products And Medical Devices Of Croatia
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