Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijos

CERTIFICATE NUMBER :***LT/01H/2020***

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 Lithuania confirms the following:
The manufacturer:***UAB "Corpus Medica"***
Site address:***Sukilėlių pr. 61-2, Kauno m. sav., Kauno m., LT-49333, Lithuania***

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
The Law on Pharmacy of the Republic of Lithuania, Article 24.

Other
has been inspected under the national inspection programme in connection with manufacturing authorisation No 0842 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: Law on Pharmacy 22 June 2006 No X-709

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-12-12*** , it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/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.*

EudraGMP

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: Storage of bulk products, medicinal products before batch certification(en)

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

2020-01-13

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

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Confidential
State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania
Tel :***Confidential***
Fax :***Confidential***

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