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Dr. Riad Armanious
~~**Head OSD QA**~~ CEO

Eva Pharma for Pharmaceuticals & Medical Appliances
176, El Sadat Str., Kafr El-Gabal, El-Haram, Giza, Egypt

Ref: OGYÉI/32896-6/2019
Subject: GMPC
Date: 10 February 2020

Dear Dr. Riad Armanious,

Please find attached the GMP certificate of your facility registered in EudraGMDP database.

Eva Pharma for Pharmaceuticals & Medical Appliances
176, El Sadat Str., Kafr El-Gabal, El-Haram, Giza, Egypt

Please consider that major changes related to the GMP system are to be reported on a yearly basis.

You are also requested to report the authorisation, manufacturing and distribution of a medicinal product in the EU, and any event, which may affect the GMP compliance.

Yours sincerely,

Dr. Mátyás Szentiványi
General Director

Digitally signed by Sîli Oleg
Date: 2021.04.02 08:49:23 EEST
Reason: MoldSign Signature
Location: Moldova

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National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: ***OGYÉI/32896-6/2019***

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 Hungary confirms the following:
The manufacturer: ***Eva Pharma for Pharmaceuticals &Medical Appliances***
Site address: ***176., El Sadat Str., Kafr El-Gabal, El-Haram, Giza, Egypt***

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 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-11-21*** , 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.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The inspection covered the manufacturing of non-sterile medicinal products for human use in Pharma building, and the manufacturing of sterile medicinal products for human use in MARC building.

2020-02-10

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

Mr. Matyas Szentivanyi
National Institute of Pharmacy and Nutrition
Tel: ***+36 18869 300***
Fax: