ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ
1475 ΛΕΥΚΩΣΙΑ

REPUBLIC OF CYPRUS
MINISTRY OF HEALTH
PHARMACEUTICAL SERVICES
1475 LEFKOSIA

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07 September 2017

MARATHON DISTRIBUTORS LTD

Inspection of the medicinal products´ manufacturing facility: MARATHON DISTRIBUTORS LTD
Inspection Number: 33/2017, Date inspection ended: 10th August 2017
Good Manufacturing Practice Certificate (GMPC), Number MARD 01/2017

Please find, herewith attached, the GMP Certificate for the above mentioned manufacturing facility.

The Certificate is issued in accordance to the provisions of article 48(8)(a) of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law No. 70(I) of 2001 *[Article 111(5) of the Directive 2001/83/EC]*.

This Certificate is also published in the EudraGMP European Database (http://eudragmp.eudra.org/).

Anna Pafitou
Head GMP Inspector

Pharmaceutical Services Ministry Of Health

CERTIFICATE NUMBER: ***MARD 01/2017***

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 Cyprus confirms the following:
The manufacturer: ***MARATHON DISTRIBUTORS LTD***
Site address: ***35 Kilkis Street, Latsia, NICOSIA, 2234, Cyprus***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***039*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
PART IV, Chapters A and B of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law No 70(I) of 2001, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-08-10*** , 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**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packing

Any restrictions related to the scope of this certificate :

Batch Certification for secondary packaging only

2017-09-07

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

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