MALTA MEDICINES AUTHORITY

IN012/08 Appendix 01 Version 1

Certificate No: **MT/022HM/2018**

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

The Medicines Authority of Malta confirms the following:

The manufacturer: **Pharmadox Healthcare Ltd.**

Site address: **KW20 Kordin Industrial Park, Paola PLA 3000, Malta**
Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040, Malta

Has been inspected under the national inspection programme in connection with manufacturer's licence no. **ML013** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation: **Medicines Act 2003 Part III Title II Art 37 and Legal Notice 490 of 2004 Regulation 13 & 14.**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **17th - 18th July 2018**, 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.

24th September 2018 .....

Dr Mark Cilia
Director IED
Medicines Authority
Tel: 00356 234 39 119
Fax: 00356 234 39 161

1 The certificate referred to in paragraph 111(5) of Directive 2001/83/EC, is also applicable to importers.
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 Human Investigational Medicinal Products	
1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS	
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*
1.6	**Quality Control testing** *1.6.1 Microbiological: sterility* *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

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2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products** *2.1.1 Microbiological: sterility* *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical*
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*

Any restrictions or clarifying remarks related to the scope of this certificate:
Luqa site is certified for warehousing purposes only.

24th September 2018 .....

Dr Mark Cilia[1]
Director IED
Medicines Authority
Tel: 00356 234 39 119
Fax: 00356 234 39 161

[1] The signature, date and contact details should appear on each page of the certificate