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Malta Medicines Authority

CERTIFICATE NUMBER: ***MT/012HM/2022***

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

Part 1

Issued following an inspection in accordance with
Art. 15 of Directive 2001/20/EC
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Malta confirms the following:
The manufacturer: ***Pharmadox Healthcare Limited***
Site address: ***Kw20a Kordin Industrial Park, Paola, PLA 3000, Malta***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012142*** / ***LOC-100018944***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***ML013 (4th variation)*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-04-21 00:00:00.0***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 15 of Directive 2001/20/EC and Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

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Part 2

Human Investigational Medicinal Products 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 packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

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

Clarifying remarks (for public users)

Re 1.5.2: Secondary packaging refers to the over labelling of the primary and secondary packaging, replacement of secondary packaging (outer carton) as well as the removal and insertion of Patient information leaflets. It does not include overprinting of the unique identifier and data matrix.

2022-03-07 00:00:00.0

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

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Confidential
Medicines Authority
Tel:***Confidential***
Fax:***Confidential***

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