WARENDORF

I, Jeroen Franciscus Antonius Aerts, civil law notary in Amsterdam, the Netherlands, hereby certify that the attached photocopy - after having been compared with the original document – is a true copy of the document shown to me.

Amsterdam, 20 June 2024.

Mr. J.F.A. AERTS
NOTARIS TE AMSTERDAM

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
   This public document
2. has been signed by **mr. J.F.A. Aerts**
3. acting in the capacity of notary at Amsterdam
4. bears the seal/stamp of aforesaid notary

Certified

5. in Amsterdam
6. on 20-06-2024
7. by the registrar of the district court of Amsterdam
8. no. 15092

9. Seal/stamp:
10. Signature:

İ. Yetkin

Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 23/2048167***

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 Netherlands confirms the following:
The manufacturer: ***Lotus Pharmaceutical Co. Ltd.***
Site address: ***Sinsing Village No 30, Chenggong 1st Rd, Nantou, 54066, Taiwan***
OMS Organisation Id. / OMS Location Id.: ***ORG-100021612 / LOC-100030323***

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 transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-12-11***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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. 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.*

Part 2

Human Medicinal Products

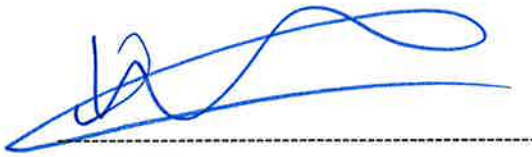
1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Cytotoxics(en) 1.2.1.2 Capsules, soft shell Special Requirements 7 Other: Cytotoxics(en) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate:

Certificate applies to manufacturing activities in Block C and G as listed above. This includes manual secondary packaging. Automated secondary packaging was not inspected and is excluded from the scope of this certificate.

2024-04-08

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



Roelof Mol
Health And Youth Care Inspectorate
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