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Location: Moldova

Norwegian Medical Products Agency

CERTIFICATE NUMBER: ***23/28995-19***

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 Norway confirms the following:
The manufacturer: ***Kexing Biopharm Co. Ltd.***
Site address: ***No 2666 Chuangye Road Bucun Street, Zhangqiu District, Jinan, 250200***
OMS Organisation Id. / OMS Location Id.: ***ORG-100024186*** / ***LOC-100079703***

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 ***2024-02-02***, 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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

Section 1.6.4 applies to endotoxin testing. \| The certificate is limited to the manufacturing performed at Workshop 301 (building 3, fourth floor), production line A, and to the product Paclitaxel WhiteOak 5 mg/ml powder for dispersion for infusion.

2024-04-30

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

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Confidential
Norwegian Medical Products Agency
Tel:***Confidential***
Fax:***Confidential***