Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/E/API/06/2024***

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 Italy confirms the following:
The manufacturer: ***Wuxi Biologics (Shanghai) Co. Ltd.***
Site address: ***31 Yiwei Road, Trade Zone, Pilot Free, 200131, China***
OMS Organisation Id. / OMS Location Id.: ***ORG-100020899*** / ***LOC-100054355***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-11-24***, 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]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

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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.

[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	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.3 Other: active substances(en)

Manufacture of active substance. Names of substances subject to inspection:
SOTROVIMAB(en)
CIPAGLUCOSIDASE ALFA(en)
SUGEMALIMAB(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:SOTROVIMAB

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.5 Other: Master Cell Bank/Working Cell Bank Production and Storage *Special Requirements:* 3.Live Cells

Active Substance:CIPAGLUCOSIDASE ALFA

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.5 Other: Master Cell Bank/Working Cell Bank Production and Storage *Special Requirements:* 3.Live Cells

Active Substance:SUGEMALIMAB

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.5 Other: Master Cell Bank/Working Cell Bank Production and Storage *Special Requirements:* 3.Live Cells

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Building 16	***Areas involved in MCB/WCB activities for DS inspection scope***			
Building 10	***Only MCB/WCB storage activity***			
			QC activities: MCB/WCB testing and releasing activities	

2024-08-08

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

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Confidential
Italian Medicines Agency
Tel:***Confidential***
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