Federal Agency for Medicines and Health Products (FAMHP)
Avenue Galilée - Galileelaan 5/03
1210 BRUSSELS (BELGIUM)
www.fagg.be – www.afmps.be - www.famhp.be

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2022/089***

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

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Belgium confirms the following:
The manufacturer: ***Syngene International Limited***
Site address: ***Plot 2 3Biocon ParkBommasandra-Jigani Link Road, Bangalore, 560099, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012176*** / ***LOC-100019570***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 33(2) of Regulation 726/2004/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-09-30***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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.

---

[1] *The certificate referred to in paragraph Art. 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[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

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.3 Other: Manufacture of biological / immunological active substance(en)
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.1 Filtration
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

The scope of the inspection and thus this certificate is limited to the manufacture of a biological active substance (a monoclonal antibody) in the mammalian cell culture suite – bedinvetmab. However, this statement of GMP compliance is on the basis that only manufacture of mammalian cells or mammalian cell based products is performed in the facilities at the same time as bedinvetmab manufacture.

2023-01-09

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

afmps fagg

Digitally signed by Séverine Brasseur (Signature)
Date: 2023.01.16 14:40:35 +01'00'

on behalf Séverine Brasseur
DG Inspection - File Manager

Xavier De Cuyper