Veterinary Medicines Directorate

Certificate No: VMDGMP/M041/2016

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Manufacturer

Part 1

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

The competent authority of: UNITED KINGDOM (***Veterinary***) confirms the following:

The manufacturer: **Syngene International Limited**

Site address: Plot No. 2 & 3, Bommasandra IV Phase
Jigani Link Road
Bangalore – 560 099
Karnataka
India

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 80(4) of Directive 2001/82/EC transposed in the following national legislation:

The Current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **12 to 16 September 2016**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

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 EudraGMP. If it does not appear, please contact the issuing authority.

Signature:

Date: 14/12/2016

Name: Dr Jason Todd
Head of Team, GMP Inspections

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Part 2

Veterinary Medicinal Products

1.	**MANUFACTURING OPERATIONS**
1.1	Sterile Products: N/A
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: 1.4.1 Manufacture of: 1.4.1.3 Other - *manufacture of biological / immunological active substance* 1.4.2 Sterilisation of active substances / excipients / finished product 1.4.2.1 Filtration
1.5	Packaging: N/A
1.6	Quality Control testing: 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical 1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate:

The scope of the inspection and thus this certificate was limited to the manufacture of a biological active substance (a monoclonal antibody) in the cell culture suite of the Biologics Pilot Plant. In addition to this suite the following associated areas / laboratories were inspected and are covered by this certificate:

- The BPP water and steam generation area
- S19 warehouse – raw materials receipt, biologics raw materials dispensing / sampling room, biologics raw materials storage
- S19 quality control laboratories – raw materials QC
- BPP quality control laboratories – in-process and finished API QC
- Microbiological quality control laboratories
- BPP seed storage room

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

Signature: 

Date: 14/12/2016

Name: Dr Jason Todd
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Veterinary Medicines Directorate
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