Veterinary Medicines Directorate

Certificate No: VMDGMP/M002/2018

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: **Bushu Pharmaceuticals Ltd**

Site address: 1 Takeno
Kawagoe
Saitama 3350-0801
Japan

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 **25th January 2018**, 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: Confidential

Date: 12th March 2018

Name: Confidential

Part 2

Veterinary Medicinal Products

1.	MANUFACTURING OPERATIONS
1.1	Sterile Products: N/A
1.2	Non-sterile products: 1.2.1.13 Tablets
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: N/A
1.5	Packaging: N/A
1.6	Quality Control testing: 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

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

1. The certificate covers the contract manufacture of bulk tablets for veterinary use only.

2. The facilities covered by this certificate are;

   - Warehousing
   - Building 6 – tablet production facilities
   - Building 1 – microbiology and chemistry QC testing suites

3. Primary and secondary packaging of finished product was outside of the scope of the inspection and is not covered by this certificate.

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

Signature: Confidential

Date: 12th March 2018

Name: Confidential

Veterinary Medicines Directorate
tel: Confidential
email: Confidential