Veterinary Medicines Directorate

Certificate No: VMDGMP/T046/2019

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Contract Test Site

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: **Elanco Canada Ltd.**
Aqua Health Business

Site address: 797 Victoria Road
Victoria
Prince Edward Island
Canada C0A 2G0

Has been inspected in connection with marketing authorisation(s) listing the company as a site of QC testing 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 contract testing site, the latest of which was conducted on **28 November 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 contract testing 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: 04 March 2019

Name: CONFIDENTIAL

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911
Search for VMD on GOV.UK

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: N/A
1.5	Packaging: N/A
1.6	Quality Control testing: 1.6.4 Biological

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

1. The *in vivo* safety and potency testing of fish vaccines.
2. This site was inspected as part of a GMP inspection of Elanco Canada's production and testing facilities in Charlottetown and Victoria, PEI. This inspection was performed from 26 – 30 November 2018. The activities at the Charlottetown facilities are covered by a separate GMP certificate.

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

Signature: _____

Date: 04 March 2019

Name: CONFIDENTIAL

Veterinary Medicines Directorate
tel: confidential
email: confidential