Veterinary Medicines Directorate

Certificate No: VMDGMP/M045/2019-rev1

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

Site address:

28 and 37 McCarville Street
Charlottetown
Prince Edward Island
Canada C1E 2A7

64 Hillstrom Avenue
Charlottetown
Prince Edward Island
Canada C1E 2C6

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 **26-30 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 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: 20 December 2021

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: 1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: 1.3.1 Biological medicinal products 1.3.1.2 Immunological products
1.4	Other products or processing activity: 1.4.1 Manufacture of: 1.4.1.3 Biological Active Starting Materials
1.5	Packaging: 1.5.2 Secondary packing
1.6	Quality Control testing: 1.6.1 Microbiological: sterility 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:

1. The manufacture including secondary packing of bacterial antigens and finished aquaculture vaccines is conducted at 37 McCarville Street.
2. The manufacture including secondary packing of viral and nucleic acid is conducted at 64 Hillstrom Avenue.
3. QC testing of antigens and vaccines is only conducted at 28 McCarville Street.

Due to the Covid-19 pandemic a planned inspection of the site has been postponed. A risk assessment has been performed and following this, the validity of this GMP certificate has been extended to 31st December 2022

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

CONFIDENTIAL

Signature: _____

Date: 20 December 2021

Name: CONFIDENTIAL